

CORRECTED VERSION

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
13 March 2003 (13.03.2003)

PCT

(10) International Publication Number  
**WO 2003/020338 A3**

(51) International Patent Classification<sup>7</sup>: **A61B 18/18**

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(21) International Application Number:  
PCT/US2002/028237

(72) Inventors; and

(22) International Filing Date:  
4 September 2002 (04.09.2002)

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(25) Filing Language: English

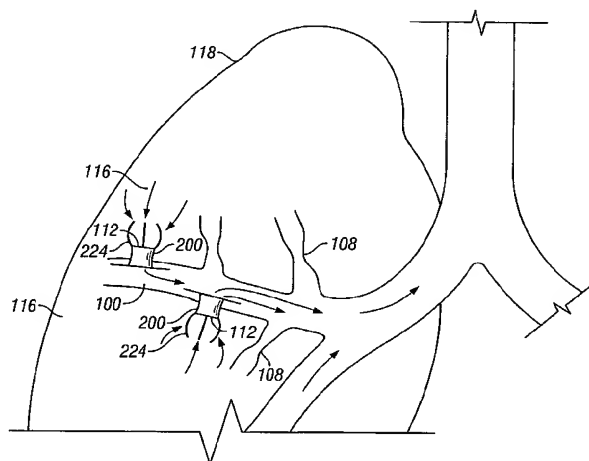
(26) Publication Language: English

(30) Priority Data:  
60/317,338 4 September 2001 (04.09.2001) US  
09/947,144 4 September 2001 (04.09.2001) US  
60/334,642 29 November 2001 (29.11.2001) US  
60/367,436 20 March 2002 (20.03.2002) US  
60/374,022 19 April 2002 (19.04.2002) US  
60/387,163 7 June 2002 (07.06.2002) US

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[Continued on next page]

(54) Title: CONDUITS HAVING DISTAL CAGE STRUCTURE FOR MAINTAINING COLLATERAL CHANNELS IN TISSUE AND RELATED METHODS



(57) Abstract: Devices and related methods are directed to altering gaseous flow within a lung to improve the expiration cycle of an individual having Chronic Obstructive Pulmonary Disease. More particularly, conduits (200) maintain collateral openings or channels through the airway wall so that air is able to pass directly out of the lung tissue to facilitate both the exchange of oxygen ultimately into the blood and to decompress hyper-inflated lungs. The conduits include a center section (310) with a passageway extending through the center section. The conduits further include a distal cage (216) structure which has a passageway and at least one opening in fluid communication with the center section passageway. The medical kits disclosed herein are also directed to maintain collateral openings through airway walls.

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ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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**Published:**

— with international search report

(81) **Designated States (national):** AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(88) **Date of publication of the international search report:**  
6 November 2003

(48) **Date of publication of this corrected version:**  
15 January 2004

(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,

(15) **Information about Correction:**

see PCT Gazette No. 03/2004 of 15 January 2004, Section II

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## **CONDUITS HAVING DISTAL CAGE STRUCTURE FOR MAINTAINING COLLATERAL CHANNELS IN TISSUE AND RELATED METHODS**

### **CROSS-REFERENCE TO RELATED APPLICATIONS**

**[0001]** This application claims the benefit of U.S. Provisional Application No. 60/317,338, filed on September 4, 2001; U.S. Provisional Application No. 60/334,642, filed on November 29, 2001; U.S. Provisional Application No. 60/367,436, filed on March 20, 2002; U.S. Provisional Application No. 60/374,022, filed on April 19, 2002; and U.S. Provisional Application No. 60/387,163, filed on June 7, 2002. This application is also a continuation in part of U.S. Application No. 09/947,144, filed September 4, 2001, which claims the benefit of U.S. Provisional Application No. 60/269,130, filed on February 14, 2001, and U.S. Application No. 09/947,144, filed September 4, 2001, is a continuation in part of U.S. Application No. 09/633,651, filed August 7, 2000, which claims the benefit of U.S. Provisional Application No. 60/147,528, filed on August 5, 1999, and U.S. Provisional Application No. 60/176,141, filed on January 14, 2000. Each of the above referenced applications is incorporated herein by reference in its entirety.

### **FIELD OF THE INVENTION**

**[0002]** The invention is directed to conduits for altering gaseous flow within a lung to improve the expiration cycle of an individual, particularly individuals having Chronic Obstructive Pulmonary Disease. The conduits maintain collateral openings or channels through the airway wall so that air is able to pass directly out of the lung tissue to facilitate both the exchange of oxygen ultimately into the blood and/or to decompress hyper-inflated lungs. The conduits generally include a center section having a passageway for air to flow through and a distal cage structure having a passageway that is in fluid communication with the center section passageway. The invention is also directed to methods and medical kits for maintaining collateral openings through airway walls.

### **BACKGROUND OF THE INVENTION**

**[0003]** In 1995, the American Lung Association (ALA) estimated that between 15-16 million Americans suffered from chronic obstructive pulmonary disease (COPD) which

includes diseases such as chronic bronchitis, emphysema, and some types of asthma. The ALA estimated that COPD was the fourth-ranking cause of death in the U.S. The ALA estimates that the rates of emphysema is 7.6 per thousand population, and the rate for chronic bronchitis is 55.7 per thousand population.

[0004] Those inflicted with COPD face disabilities due to the limited pulmonary functions. Usually, individuals afflicted by COPD also face loss in muscle strength and an inability to perform common daily activities. Often, those patients desiring treatment for COPD seek a physician at a point where the disease is advanced. Since the damage to the lungs is irreversible, there is little hope of recovery. Most times, the physician cannot reverse the effects of the disease but can only offer treatment and advice to halt the progression of the disease.

[0005] To understand the detrimental effects of COPD, the workings of the lungs requires a cursory discussion. The primary function of the lungs is to permit the exchange of two gasses by removing carbon dioxide from arterial blood and replacing it with oxygen. Thus, to facilitate this exchange, the lungs provide a blood gas interface. The oxygen and carbon dioxide move between the gas (air) and blood by diffusion. This diffusion is possible since the blood is delivered to one side of the blood-gas interface via small blood vessels (capillaries). The capillaries are wrapped around numerous air sacs called alveoli which function as the blood-gas interface. A typical human lung contains about 300 million alveoli.

[0006] The air is brought to the other side of this blood-gas interface by a natural respiratory airway, hereafter referred to as a natural airway or airway, consisting of branching tubes which become narrower, shorter, and more numerous as they penetrate deeper into the lung. Specifically, the airway begins with the trachea which branches into the left and right bronchi which divide into lobar, then segmental bronchi. Ultimately, the branching continues down to the terminal bronchioles which lead to the alveoli. Plates of cartilage may be found as part of the walls throughout most of the airway from the trachea to the bronchi. The cartilage plates become less prevalent as the airways branch. Eventually, in the last generations of the bronchi, the cartilage plates are found only at the branching points. The bronchi and bronchioles may be distinguished as the bronchi lie proximal to the last plate of cartilage found along the airway, while the bronchiole lies distal to the last plate of cartilage. The bronchioles are the smallest airways that do not contain alveoli. The function of the bronchi and bronchioles is to provide conducting



airways that lead air to and from the gas-blood interface. However, these conducting airways do not take part in gas exchange because they do not contain alveoli. Rather, the gas exchange takes place in the alveoli which are found in the distal-most end of the airways.

[0007] The mechanics of breathing include the lungs, the rib cage, the diaphragm and abdominal wall. During inspiration, inspiratory muscles contract increasing the volume of the chest cavity. As a result of the expansion of the chest cavity, the pleural pressure, the pressure within the chest cavity, becomes sub-atmospheric. Consequently, air flows into the lungs and the lungs expand. During unforced expiration, the inspiratory muscles relax and the lungs begin to recoil and reduce in size. The lungs recoil because they contain elastic fibers that allow for expansion, as the lungs inflate, and relaxation, as the lungs deflate, with each breath. This characteristic is called elastic recoil. The recoil of the lungs causes alveolar pressure to exceed atmospheric pressure causing air to flow out of the lungs and deflate the lungs. If the lungs' ability to recoil is damaged, the lungs cannot contract and reduce in size from their inflated state. As a result, the lungs cannot evacuate all of the inspired air.

[0008] In addition to elastic recoil, the lungs' elastic fibers also assist in keeping small airways open during the exhalation cycle. This effect is known as "tethering" of the airways. Such tethering is desirable since small airways do not contain cartilage that would otherwise provide structural rigidity for these airways. Without tethering, and in the absence of structural rigidity, the small airways collapse during exhalation and prevent air from exiting thereby trapping air within the lung.

[0009] Emphysema is characterized by irreversible biochemical destruction of the alveolar walls that contain the elastic fibers, called elastin, described above. The destruction of the alveolar walls results in a dual problem of reduction of elastic recoil and the loss of tethering of the airways. Unfortunately for the individual suffering from emphysema, these two problems combine to result in extreme hyperinflation (air trapping) of the lung and an inability of the person to exhale. In this situation, the individual will be debilitated since the lungs are unable to perform gas exchange at a satisfactory rate.

[0010] One further aspect of alveolar wall destruction is that the airflow between neighboring air sacs, known as collateral ventilation or collateral air flow, is markedly increased as when compared to a healthy lung. While alveolar wall destruction decreases resistance to collateral ventilation, the resulting increased collateral ventilation does not

benefit the individual since air is still unable to flow into and out of the lungs. Hence, because this trapped air is rich in CO<sub>2</sub>, it is of little or no benefit to the individual.

[0011] Chronic bronchitis is characterized by excessive mucus production in the bronchial tree. Usually there is a general increase in bulk (hypertrophy) of the large bronchi and chronic inflammatory changes in the small airways. Excessive amounts of mucus are found in the airways and semisolid plugs of this mucus may occlude some small bronchi. Also, the small airways are usually narrowed and show inflammatory changes.

[0012] Currently, although there is no cure for COPD, treatment includes bronchodilator drugs, and lung volume reduction surgery. The bronchodilator drugs relax and widen the air passages thereby reducing the residual volume and increasing gas flow permitting more oxygen to enter the lungs. Yet, bronchodilator drugs are only effective for a short period of time and require repeated application. Moreover, the bronchodilator drugs are only effective in a certain percentage of the population of those diagnosed with COPD. In some cases, patients suffering from COPD are given supplemental oxygen to assist in breathing. Unfortunately, aside from the impracticalities of needing to maintain and transport a source of oxygen for everyday activities, the oxygen is only partially functional and does not eliminate the effects of the COPD. Moreover, patients requiring a supplemental source of oxygen are usually never able to return to functioning without the oxygen.

[0013] Lung volume reduction surgery is a procedure which removes portions of the lung that are over-inflated. The improvement to the patient occurs as a portion of the lung that remains has relatively better elastic recoil which allows for reduced airway obstruction. The reduced lung volume also improves the efficiency of the respiratory muscles. However, lung volume reduction surgery is an extremely traumatic procedure which involves opening the chest and thoracic cavity to remove a portion of the lung. As such, the procedure involves an extended recovery period. Hence, the long term benefits of this surgery are still being evaluated. In any case, it is thought that lung volume reduction surgery is sought in those cases of emphysema where only a portion of the lung is emphysematous as opposed to the case where the entire lung is emphysematous. In cases where the lung is only partially emphysematous, removal of a portion of emphysematous lung which was compressing healthier portions of the lung allows the healthier portions to expand, increasing the overall efficiency of the lung. If the entire lung is emphysematous, however, removal of a portion of the lung removes gas exchanging alveolar surfaces,

reducing the overall efficiency of the lung. Lung volume reduction surgery is thus not a practical solution for treatment of emphysema where the entire lung is diseased.

[0014] Both bronchodilator drugs and lung volume reduction surgery fail to capitalize on the increased collateral ventilation taking place in the diseased lung. There remains a need for a medical procedure that can alleviate some of the problems caused by COPD. There is also a need for a medical procedure that alleviates some of the problems caused by COPD irrespective of whether a portion of the lung, or the entire lung is emphysematous. The production and maintenance of collateral openings through an airway wall allows air to pass directly out of the lung tissue responsible for gas exchange. These collateral openings serve to decompress hyper inflated lungs and/or facilitate an exchange of oxygen into the blood.

[0015] Methods and devices for creating, and maintaining collateral channels are discussed in U.S. Patent Application No. 09/633,651, filed on August 7, 2000; U.S. Patent Application Nos. 09/947,144, 09/946,706, and 09/947,126 all filed on September 4, 2001; U.S. Provisional Application No. 60/317,338 filed on September 4, 2001; U.S. Provisional Application No. 60/334,642 filed on November 29, 2001; U.S. Provisional Application No. 60/367,436 filed on March 20, 2002; and U.S. Provisional Application No. 60/374,022 filed on April 19, 2002 each of which is incorporated by reference herein in its entirety.

[0016] Events that may arise when a device is implanted in a surgically-created channel in a lung is that the device can be ejected, filled in with tissue, or otherwise rendered ineffective as the wound heals. It is desirable to provide a device which is capable of providing long-term patency of surgically-created channels in the lung and, in particular, to provide a device which is less susceptible to the above mentioned events.

## SUMMARY OF THE INVENTION

[0017] This invention relates to devices and methods for altering gaseous flow in a lung. The invention includes a conduit for maintaining the patency of an opening in tissue. In one variation of the present invention, a conduit comprises a center section having a first end, a second end and a center-section passageway extending from the first end to the second end. The conduit further comprises a plurality of first extension members extending from the first end. The first extension members are outwardly deflectable about the first end of the center section. The conduit further comprises a cage structure adjacent to the

second end of the center section. The cage structure has at least one opening and a cage passageway in fluid communication with the center-section passageway.

[0018] The cage structure may connect directly to the second end of the center section or it may connect to the center section via a plurality of deflectable distal extension members which are joined to the second end of the center section. The cage may be formed of a single element or alternatively, the cage may be formed of a plurality of cage segments or members. Also, portions of the conduit may be coaxially surrounded with a tissue barrier or membrane to prevent tissue growth into the passageway of the conduit.

[0019] The conduit may have an undeployed state for facilitating delivery of the conduit to a target site and a deployed state, different than the undeployed state, for maintaining the patency of a channel in an airway wall. In this variation of the present invention the conduit comprises a radially expandable frame having a proximal section, a center section and a distal section. The proximal section comprises a plurality of proximal extension members. The center section comprises a first end at which the plurality of proximal extension members are attached. The center section further includes a second end and a center-section passage extending from the first end to the second end. The distal section of the frame comprises a cage having at least one opening and a cage passage which is in fluid communication with the center-section passage. When the conduit is in the undeployed state the proximal section, the center section, and the distal section have a reduced profile. When the conduit is in the deployed state, the plurality of extension members deflect outward forming a non-zero angle with an axis of the center-section passage, and the cage has an expanded profile greater than that of the cage when the conduit is in the undeployed state. Additionally, a biocompatible coating may coaxially surround at least a portion of the frame.

[0020] In another variation of the present invention a conduit comprises a center section having a proximal end, a distal end, and a passage within the center section extending between the ends. The conduit further comprises a plurality of extension members with at least one proximal extension member and at least one distal extension member. The proximal extension members have a fixed end attached to the proximal end of the center section and the distal extension members have a fixed end attached to the distal end of the center section. Also, each of the proximal and distal extension members have a free end being moveable such that the extension members may rotate about each of the ends of the center section to retain tissue between the extension members. The conduit further includes

a cage adjacent to the distal end of the center section. The cage has at least one opening and a passage in fluid communication with the center section passage.

[0021] A method for maintaining the patency of a channel in lung tissue comprises deploying a medical device in the channel wherein the medical device has a passageway extending from one open end to a second open end. The medical device may be a conduit as recited herein. Also, the deploying step may be carried out using a balloon catheter having an inflatable member. The method may also comprise delivering a bioactive substance to the tissue. The bioactive substance may be a coating on the conduit. Additionally, the substance may be delivered by a delivery catheter prior to deploying the conduit.

[0022] A kit comprises a conduit as recited herein. The kit additionally comprises a deployment catheter to deploy the conduit. The deployment catheter may be a balloon catheter. The kit may further comprise an instrument for creating holes in an airway wall. The instrument may also have the capability to detect blood vessels when creating channels in the airway wall. The kit may further comprise a guidewire.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Figures 1A-1C illustrate various states of the natural airways and the blood-gas interface.

[0024] Figures 1D and 1E illustrate a schematic of a lung having conduits deployed in channels to alter airflow through the lung.

[0025] Figure 2A illustrates a planar view of a surface of a variation of a conduit.

[0026] Figure 2B illustrates a perspective view of the conduit of Figure 2A in an un-deployed state.

[0027] Figure 2C illustrates a perspective view of the conduit of Figure 2A in a deployed state.

[0028] Figure 3 illustrates an unexpanded planar view of a surface of a variation of a conduit in which cage members extend perpendicularly to distal extension members prior to deployment of the device.

[0029] Figures 4 and 5 illustrate planar views of variations of conduits.

[0030] Figure 6 illustrates a planar view of a variation of a conduit wherein the proximal and distal extension members are in an alternating pattern.

[0031] Figure 7A illustrates a planar view of a variation of a conduit of the present invention wherein the cage is attached to distal extension members.

[0032] Figure 7B illustrates a perspective view of the conduit of Figure 7A in a deployed state.

[0033] Figure 8A illustrates a planar view of a variation of a conduit wherein the distal extension member is non-planar.

[0034] Figure 8B illustrates a side view of the conduit of Figure 8A.

[0035] Figure 8C illustrates a perspective view of the conduit of Figure 8B.

[0036] Figure 9A illustrates a planar view of a variation of a conduit.

[0037] Figure 9B illustrates a perspective view of the conduit of Figure 9A in an un-deployed state.

[0038] Figure 9C illustrates a perspective view of the conduit of Figure 9A in a deployed state.

[0039] Figure 9D illustrates a perspective view of another conduit in a deployed state.

[0040] Figure 9E illustrates a side view of a conduit in an un-deployed state.

[0041] Figure 9F illustrates a side view of the conduit of Figure 9E shown in a deployed state.

[0042] Figure 9G illustrates a front view of the conduit shown in Figure 9F.

[0043] Figure 9H is a cylindrical projection of the undeployed conduit shown in Figure 9E.

[0044] Figure 9I illustrates a side view of another conduit in an undeployed state.

[0045] Figure 9J illustrates a side view of the conduit of Figure 9I in a deployed state.

[0046] Figure 9K is a cylindrical projection of the undeployed conduit shown in Figure 9I.

[0047] Figures 9L-9P illustrate variations of conduits.

[0048] Figures 10A-10D illustrate a variation of the conduit having length-increasing portions on the cage members of the conduit.

[0049] Figure 11 illustrates a cross sectional view of a variation of a conduit having an inner covering.

[0050] Figures 12A-12B illustrate views of a conduit having a filler material between openings in ribs.

[0051] Figures 13A-13C illustrate views of a conduit having reduced thickness or weakened sections.

[0052] Figure 14A illustrates a variation of a conduit having a tissue barrier.

[0053] Figure 14B illustrates a side view of another conduit having a tissue barrier.

- [0054] Figure 14C is a front view of the conduit shown in Figure 14B.
- [0055] Figure 14D illustrates a conduit positioned in a channel created in a tissue wall.
- [0056] Figure 14E is a cross sectional view of the conduit shown in Figure 14B taken along line 14E-14E.
- [0057] Figures 14F-14K illustrate additional variations of conduits.
- [0058] Figure 15A illustrates a perspective view of another conduit.
- [0059] Figure 15B illustrates a side view of the conduit of Figure 15A.
- [0060] Figure 15C-15D illustrate planar views of a surface of the conduit shown in Figure 15A.
- [0061] Figure 15E and 15F illustrate a side view of the conduit of Figure 15A prior to deployment of the proximal extension members and cage members.
- [0062] Figure 16A illustrates a planar view of a surface of a variation of a conduit.
- [0063] Figure 16B illustrates a perspective view of the conduit of Figure 16A in a deployed state.
- [0064] Figure 16C illustrates a planar view of another variation of a conduit.
- [0065] Figure 16D illustrates a side view of the conduit shown in Figure 16C in a deployed configuration.
- [0066] Figure 16E illustrates a side view of another conduit having a tissue barrier and a visualization marker.
- [0067] Figure 17A illustrates a side view of another conduit.
- [0068] Figure 17B illustrates a side view of the conduit shown in Figure 17A after the conduit is deployed.
- [0069] Figure 17C illustrates a front view of the conduit shown in Figure 17B.
- [0070] Figures 17D-17E illustrate a variation of a conduit where the conduit comprises a wire or mesh pattern.
- [0071] Figure 17F illustrates another variation of a conduit.
- [0072] Figures 18A-18F illustrate a method for deployment of a conduit.
- [0073] Figures 19A-19C illustrate the deployment of a conduit.
- [0074] Figures 20A-20B illustrate the deployment of a conduit.
- [0075] Figures 21A-21C illustrate the deployment of a conduit using a balloon catheter.
- [0076] Figure 21D illustrates another variation of a balloon catheter which may be used to deploy a conduit.

[0077] Figures 22A-22D illustrate another variation of a deployment catheter which may be used to deploy conduits.

[0078] Figures 23A-23C illustrate the use of a guide member in assisting the placement of a conduit.

[0079] Figure 24 illustrates a variation of a conduit having a one-way valve.

[0080] Figures 25A-25B illustrate a method for deploying a conduit at an angle.

## DETAILED DESCRIPTION OF THE INVENTION

[0081] Described herein are devices (and methods) for improving the gas exchange in the lung. In particular, a conduit is described which serves to maintain collateral openings or channels through an airway wall so that air is able to pass directly out of the lung tissue and into the airways. This facilitates exchange of oxygen into the blood and decompresses hyper inflated lungs.

[0082] By "channel" it is meant to include, but not be limited to, any opening, hole, slit, channel or passage created in the airway wall. The channel may be created in tissue having a discrete wall thickness and the channel may extend all the way through the wall. Also, a channel may extend through lung tissue which does not have well defined boundaries such as, for example, parenchymal tissue.

[0083] As stated above, the conduits described herein may improve airflow through an airway in the lung. Simplified illustrations of various states of a natural airway and a blood gas interface found at a distal end of those airways are provided in Figures 1A-1C. Figure 1A shows a natural airway **100** which eventually branches to a blood gas interface **102**. Figure 1B illustrates an airway **100** and blood gas interface **102** in an individual having COPD. The obstructions **104** impair the passage of gas between the airways **100** and the interface **102**. Figure 1C illustrates a portion of an emphysematous lung where the blood gas interface **102** expands due to the loss of the interface walls **106** which have deteriorated due to, for example, a bio-chemical breakdown of the walls **106**. Also depicted is a constriction **108** of the airway **100**. It is generally understood that there is usually a combination of the phenomena depicted in Figures 1A-1C. Often, the states of the lung depicted in Figures 1B and 1C may be found in the same lung.

[0084] Figures 1D and 1E schematically illustrate airflow in a lung **118** when conduits **200** are placed in collateral channels **112**. As shown, collateral channels **112** (located in an



airway wall) place lung tissue **116** in fluid communication with airways **100** allowing air to pass directly out of the airways **100** avoiding constricted airways **108** which may ordinarily prevent air from exiting the lung tissue **116**. The conduits shown in Figures 1D and 1E have cage structures **212**, **224** respectively which serve to separate parenchymal tissue, prevent occlusion of the passageway, and improve air-flow through the conduit/collateral channel. The cage or basket structures may vary widely in shape and construction as will be described herein.

[0085] Also, while the invention is not limited to the number of collateral channels which may be created, it is preferable that 1 or 2 channels are placed per lobe of the lung. For example, the preferred number of channels is 2-12 channels per individual patient. However, as stated above, the invention includes the creation of any number of collateral channels in the lung. This number may vary on a case by case basis. For instance, in some cases an emphysematous lung may require 3 or more collateral channels in one or more lobes of the lung.

[0086] In the following explanation of figures, similar numerals may represent similar features for the different variations of the invention.

[0087] Figure 2A illustrates a planar view of a surface of a variation of a conduit **200**. For purposes of illustration, the conduit **200** depicted in Figure 2A is shown as though the conduit **200** were longitudinally cut and opened. Figures 2B and 2C show the device in pre-deployed and deployed positions as discussed below. As illustrated, the conduit **200** comprises a center section **202**, having proximal **204** and distal **206** ends. Although not illustrated in this figure, the center section **202** will define a passage which extends between its ends **204**, **206**. The conduit **200** also comprises at least one proximal extension member **208** at a proximal **204** end of the center section **202** and at least one distal extension member **210** at a distal **206** end of the center section **202**. Although the conduit **200** depicted in the illustration contains 4 proximal and distal extension members **208**, **210**, the invention is not limited as such.

[0088] The conduits **200** of the present invention are not limited to any particular number of extension members. The number of proximal extension members may differ from the number of distal extension members for a particular conduit. The extension members will be selected such that they contain a fixed end that is attached to the respective end of the center section, and a movable (or free) end that is moveable such that the extension member is able to rotate or bend about the end of the center section. When the extension

members rotate about the center section of the conduit, they are able to retain tissue therebetween thus preventing significant migration of the conduit. Accordingly, one function of the extension members is that they prevent migration of the inventive conduit from its deployed position within a collateral channel. The extension members may have openings to permit tissue ingrowth for improved retention within the lung. The opening may be used to anchor a tissue barrier that is located over a portion of the conduit. Alternatively, the extension members may be solid.

[0089] Figures 2A-2C illustrate a variation of a conduit **200** as having a cage **212**. The cage **212** will define a passage (not shown) that is in fluid communication with a passage of the center section (not shown). This permits airflow through the conduit **200** in accordance with one of the benefits of the invention disclosed herein. In this variation, the cage **212** comprises a plurality of cage members **214**. In use, the conduit **200** may be deployed with the distal **206** or cage side towards the parenchymal tissue while the proximal side **204** remains adjacent or in the airway.

[0090] Variations of the invention may include conduits **200** having expandable cages **212**. Expansion of the cage **212** in the parenchymal tissue permits an increased surface area within the parenchyma to allow for improved air flow.

[0091] The presence of the cage may prevent flaps or portions of the parenchymal tissue from obstructing the passage of the center section. The cage may be effective immediately/dynamically as well as over time as the tissue heals.

[0092] Accordingly, in an unexpanded state, a portion of the cage **212** defines a first diameter and once expanded, the same portion of the cage **212** defines a second increased diameter. It is noted that the term diameter is not intended to limit the cage **212** to a cylinder or other constant diameter structure. Instead, the cage **212** may start with a constant diameter and is then expanded to have either a constant diameter, or a varying diameter (e.g., conical shape, rectangular shape, basket, other non-constant-diameter shape, or an asymmetrical shape.) Additionally, the center section **202** may or may not be expandable. In those cases where the center section **202** is expandable, once expanded, the diameter may be constant or vary (e.g., conical, hour-glass-shaped, hemi-toroidal, or other.)

[0093] Additionally, in some designs, one portion of the conduit may be radially expandable and another portion may not be radially expandable. For example, the center section may be designed as a hollow tubular member that is unexpandable. An expandable

cage may be joined to the center section. Accordingly, a conduit may have various sections some of which are expandable and others which are not expandable.

[0094] The first diameter of the cage may be selected such that the conduit is small enough to fit within an airway, a Bronchoscope or another type of delivery instrument. The second diameter of the cage usually refers to the diameter of the cage after deployment. The relationship of the second diameter to the first diameter may be related as a ratio ranging from 1:1 to 4:1 or perhaps, 2:1 to 4:1. In the unexpanded state, the first diameter of the cage may range between 0.5 mm and 3 mm (including any range therebetween.) In the expanded state, the second diameter of the cage may range between 3 mm and 10 mm (including any range therebetween).

[0095] The axial length of the center section or passageway may be relatively short. In some cases, the center-section passageway's length is about equal to the width of a wire segment or rib. The center section serves as a bridge or junction for the extension members and it is not required to be long. The axial length of the center-section passageway may therefore be less than 6 mm, less than 1 mm and even approach 0 mm. In one example, the length of the center section is less than twice the square root of a cross sectional area of the center section. However, the center section may also have passageways which have lengths greater than 1 mm.

[0096] The cage of the inventive conduit may have an axial length between 2 mm and 20 mm. The axial length will be measured along an axis of the passage of the conduit.

[0097] Cage 212 may be formed from an ordinary wire mesh that functions to keep parenchymal tissue separated to increase airflow through the conduit 200 passage. However, in the variation depicted in Figure 2A, the cage 212 comprises a plurality of cage members 214 each of which is connected to a distal extension member 210. However, as will be discussed further below, it is contemplated that the invention also includes variations where cage members connect directly to the distal 206 end of the center section 202.

[0098] As shown in Figures 2A-2C, the cage 212 may comprise a plurality of control segments 216 which interconnect at least two cage members 214 (e.g., adjacent cage members). However, it is contemplated that variations of the inventive conduit may be designed without such control segments. One of the functions of the control segments 216 includes controlling the diameter of the cage 212 during expansion and/or prevention of over-expansion of the cage 212. Furthermore, the control segments described herein may

be used to assist the conduit (or sections of the conduit) in achieving a desired profile upon expansion or deployment of the conduit. For example, the control segments may limit the expanded diameter to varying degrees along the axial length of the conduit.

[0099] Figure 2A also illustrates the cage 212 as having openings 220. In this variation, the openings 220 of the cage 212 are defined by the cage members 214.

[0100] Figure 2B illustrates a three-dimensional view of the conduit 200 of Figure 2A, wherein the conduit 200 is in an un-deployed state. Figure 2C illustrates a three-dimensional view of a conduit 200 of Figure 2B after deployment of the conduit 200. The cage is in an expanded state in Figure 2C. As illustrated, the proximal and distal extension members 208, 210 pivot (or rotate radially from a longitudinal axis of the device) around the center section 202 such that the extension members 208, 210 hold the conduit within a collateral channel. More specifically, tissue may be retained between extension members 208, 210 on the outer perimeter of the center section 202.

[0101] The conduit of the present invention may also be adapted to have a cage that is flexible. For instance, in the conduit 200 illustrated in Figure 2B, cage 212 may be flexible so as to bend and flex when it contacts an object such as lung parenchyma, blood vessels, or adjacent airways, etc. Such flexibility may be achieved by making the cage members 214 (and control segments 216) sufficiently thin, or by designing them to have a sufficiently low elastic modulus. Such a flexible cage may prevent formation of scar tissue or erosion of adjoining tissues.

[0102] To facilitate deployment of the conduit of the present invention, the conduits described herein may have proximal extension members, distal extension members, and cages which are adapted to take a pre-determined form. For example, as will be discussed further herein, the conduit could be designed to have weakened sections at specific transition points to facilitate the conduit taking a desired shape.

[0103] The conduit of the present invention may also have a pre-set shape that is assumed upon deployment within a collateral channel. In such a case, the conduit may have a pre-deployment shape, either by being restrained (e.g., if the conduit is formed from a metal such as Nitinol and is elastically restrained into the pre-deployment shape), or by other measures that require actuation (e.g., as is the case with a shape-memory alloy which assumes a shape upon reaching a certain temperature.)

[0104] Figure 3 illustrates an un-expanded planar view of a conduit 200 having a center section 202. The conduit 200 includes a plurality of proximal extension members 208 on a

side of the center section 202. In the variation depicted in Figure 3, the conduit 200 contains two distal extension members 210 from which a plurality of cage members 214 extend. As shown, the cage members 214 may contain openings to facilitate airflow, or, the cage members may be solid.

[0105] Figures 4 and 5 illustrate additional variations of conduits 200 in which the cage 212 is attached to a center section 202 of the conduit 200. In these variations, the center section 202 of the conduit 200 is located between proximal and distal extension members 208, 210. A proximal end 222 of the cage 212 is attached to the center section 202 of the conduit 200 via cage members 214 that extend between the distal extension members 210. The cage 212 may contain openings 220. The openings 220 may have a circular or oval geometries as illustrated. However, it is contemplated that the openings 220 are not limited to the particular geometry illustrated nor are the openings limited to the placement shown. For example, a conduit 200 could contain openings towards a distal end of the cage (as shown) and/or towards a proximal end of the cage (as discussed below). Furthermore, as illustrated in Figure 4, the extension members may have reduced cross sectional areas 224 which increase the ability of the extension member to rotate about the end of the center section 202. Figure 5 illustrates a variation of a conduit 200 in which the extension members extend in similar directions. Note that in this variation, the center section 202 will contain openings as the distal extension members 210 rotate away from the conduit 200. While not necessary, the center sections of conduits may be solid, e.g., to prevent tissue in-growth. Accordingly, a liner (not shown) could be placed in the passage of any center section that contains openings.

[0106] Figure 6 illustrates another variation of a conduit 200 in which the proximal extension members 208 and distal extension members 210 are in an alternating pattern as opposed to an in-line pattern.

[0107] Figure 7A illustrates another variation of an inventive conduit 200 in which a proximal end 222 of cage members 214 are attached to a free (or movable) end of the distal extension members 210. Accordingly, as the distal extension members 210 rotate about the center section 202 of the conduit 200, the cage 212 expands via expansion of the cage members 214. As illustrated, the conduit 200 may optionally have openings 220 between adjacent cage members 214. Although not illustrated, but as discussed above, the conduit may have openings on a distal portion of the cage 212 as well.

[0108] Figure 7B illustrates a perspective view of the conduit 200 of Figure 7A in a deployed position. As shown, the conduit 200, includes proximal extension members 208 and distal extension members 210 which are rotated about a center section 202 of the conduit 200. The cage 212 includes cage members 214 which have a proximal end 222 that is attached to a free end of the distal extension member 210. The cage 212 is shown to be in an expanded position and contains openings 220 which are intended to separate parenchymal tissue and allow for improved airflow through a passage 218 of the conduit 200. Additionally, although not shown in Figure 7B, the passage 218 may extend through the conduit 200 and exit from a distal end of the cage 212. As discussed above, the cage 212 may optionally have additional openings on a distal end to further increase the airflow through the conduit passage 218.

[0109] Figure 8A illustrates another variation of an inventive conduit 200 having proximal and distal extension members 208, 210 and a cage 212 having a proximal end 222 attached to an end of a center section 202 of the conduit 200. The cage 212 also contains a number of openings 220 at a distal end thereof. The conduit 200 of Figure 8A contains distal extension members 210 having a central portion 226 located between a free end 228 and a fixed end 230 of the extension member 210 where the free end 228 of the extension member 210 is non-planar with a plane defined by both the central portion 226 and the fixed end 230 of the extension member 210.

[0110] Figure 8B provides a cross-sectional view of the conduit 200 of Figure 8A and illustrates the central portion 226 of the extension member 210 as being non-planar with a plane defined by both the central portion 226 and the fixed end 230 of the extension member 210. Accordingly, as the conduit 200 is deployed, the central portion 226 is moved in an outward direction and aligns with the center section 202 of the conduit 200 causing the free end 228 of the extension member 210 to extend radially outward from the conduit 200. As a result, tissue may be secured between the free end 228 of the distal extension member 210 and the proximal extension member 208.

[0111] Figure 8C illustrates a perspective view of the conduit 200 of Figure 8B. As illustrated, the conduit 200 includes a number of proximal extension members 208 rotated about a center section 202 which contains a passage 218. Each distal extension member 210 contains a central portion 226 that is non-planar with a plane defined by the central portion 226 and the fixed end 230 of the extension member 210. As discussed above, as the central portion 226 is moved in an outward direction and aligns with the center section

**202** of the conduit **200**, the free end **228** of the extension member **210** extends radially outward from the conduit **200**. As demonstrated by this variation, some conduits may be configured such that openings in the conduit **200** are placed within the collateral channel. Accordingly, a barrier layer or an inner covering **232** may be placed within the passage **218** of the center section **202** to prevent tissue in-growth. The inner covering **232** may be a tube or coating. Furthermore, the inner covering **232** may be sufficiently flexible such that the distal extension members **210** may deflect the inner covering **232** prior to deployment of the extension members **210**.

[0112] Figures 9A-9C illustrate an additional variation of a conduit. The conduit **200** comprises a center section **202** and proximal and distal extension members **208**, **210** on either end of the center section **202**. As shown in Figure 9A and 9B, segments **236** of the center section **202** may be folded such that a diameter of the center section **202** may be minimized prior to deployment of the conduit **200**. Figure 9C illustrates expansion of the center section **202** (usually upon deployment) where the center section segments **236** control the expansion of the diameter of the center section **202**.

[0113] As noted throughout this disclosure, the number of extension members **208**, **210** may vary as required. Accordingly, the number of center section segments **202** may be dependent upon the number of extension members **208**, **210**. However, it is contemplated that center section segments **236** may be independent from the number of extension members **208**, **210**. For example, a conduit **200** of the present invention may only have 1 or more such center section segments **236** within the center section **202**.

[0114] Figure 9A also illustrates proximal and distal extension members **208**, **210** having proximal and distal control segments **238**, **240**. The control segments **238**, **240** may connect at least two extension members to control expansion of the extension members upon deployment of the conduit **200**. As described herein, upon deployment, the extension members **208**, **210** rotate about the center section **202** thereby retaining (or sandwiching) tissue between the extension members **208**, **210**. The proximal and distal control segments **238**, **240** may limit the extent to which the extension members **208**, **210** rotate, and/or prevent them from over-expanding. Although the control segments **238**, **240** are illustrated as being on the ends of the extension members **208**, **210**, the invention is not limited as such. For instance, the control segments **238**, **240** may be placed anywhere along the extension members **208**, **210**.

[0115] Figure 9A also illustrates the conduit **200** as having a cage **212** which includes a plurality of control segments **216** which interconnect at least two cage members **214** (e.g., adjacent cage members). As discussed above, the control segments **216** may control the diameter of the cage **212** during expansion and/or prevention of over-expansion of the cage **212**.

[0116] It is further noted that Figures 9A-9C do not illustrate the inventive conduit **200** as having a tissue barrier. However, the tissue barrier is omitted for purposes of illustrating the frame of the conduit **200**. It is contemplated that a tissue barrier, as described herein, may extend over the center section **202** of the conduit **200**. Moreover, variations of the invention include conduits **200** with a tissue barrier located over the proximal extension members **208**, the center section **202**, distal extension members **210** or over any combination of these features. In such cases, the openings **242** in the extension members may be used to further anchor the tissue barrier.

[0117] Figure 9B illustrates the conduit **200** of Figure 9A in a pre-deployment position. Figure 9C illustrates the conduit **200** of Figure 9A in a deployed position. As illustrated, the proximal and distal control segments **238**, **240** control expansion and rotation of the respective extension members. Also, the cage control segments **216** prevent or control expansion of the cage **212**. Furthermore, Figure 9C illustrates the expansion of center section **202** of the conduit where the center section portions **236** unfold to control expansion of the center section **202**. In variations of the conduit **200** that are deployed with a balloon, the center section portions **236** assist in causing the proximal and distal extension members **208**, **210** to bend about the center section to capture tissue therebetween. As discussed above, the number of control segments or center section portions is not limited to that which is illustrated. Instead, the number of these components may be varied as needed.

[0118] Figure 9D illustrates a variation of a conduit **200** having multiple control segments **216** between adjacent cage members **214**. One advantage of such a configuration is that the multiple control segments **216** may better control the expansion of the cage **212** preventing over-expansion of a portion thereof, or the control segments **216** may be configured to permit the cage **212** to assume a desired profile.

[0119] It is noted that the invention is not limited to having all of the control segments **216**, **238**, and **240** on each respective portion of the conduit **200**. Instead, control segments **216**, **238**, and **240** may be found on one or more portions of the conduit **200**.



[0120] Control segments may be incorporated into conduits with or without cage structures. The conduit 200 shown in Figures 9E-9H, for example, lacks a cage and includes diametric-control segments (tethers or leashes) 235 to control and limit the expansion of the center section 208 when deployed. This center-control segment 235 typically is shaped such that when the conduit radially expands, the center-control segment bends until it is substantially straight or no longer slack. Such a center-control segment 235 may be circular or annular shaped. However, its shape may vary widely and it may have, for example, an arcuate, semi-circular, V, or other type of shape which limits the expansion of the conduit. Also, while these figures show a center control segment on conduits without elongate cage members, the invention is not so limited. Center control segments may be incorporated into conduits having cage structures or into other types of conduits as discussed above.

[0121] Referring to Figures 9E-9H, one end of the center-control segment is attached or joined to the center section at one location (e.g., a first rib) and the other end of the center-control segment is connected to the center section at a second location (e.g., a rib adjacent or opposite to the first rib). However, the center-control segments may have other constructs. For example, the center-control segments may connect adjacent or non-adjacent center section members. Further, each center-control segment may connect one or more ribs together. The center-control segments may be doubled up or reinforced with ancillary control segments to provide added control over the expansion of the center section. The ancillary control segments may be different or identical to the primary control segments.

[0122] Figure 9F illustrates the conduit 200 in a deployed configuration. As discussed above, the center-control segments 235 may bend or otherwise deform until they maximize their length (i.e., become substantially straight) such as the center-control segments 235 shown in Figure 9F. However, the invention is not so limited and other types of center-control segments may be employed.

[0123] Figure 9G illustrates a front view of a conduit 200 in a deployed state. The cross section of the center section is shown as a circular or hexagonal shape. However, the invention is not so limited. The cross section of an implant may be circular, oval, rectangular, elliptical, or any other multi-faceted or curved shape. Also, the inner diameter ( $D_1$ ) of the center section, when deployed, may range from 1 to 10 mm and perhaps, from 2 to 5 mm. Moreover, in some variations, the cross-sectional area of the passageway, when

deployed, may be between  $0.2 \text{ mm}^2$  to  $300 \text{ mm}^2$  and perhaps between  $3 \text{ mm}^2$  and  $20 \text{ mm}^2$ . The diameter of the center section, when deployed, thus may be significantly larger than the passageway's axial length (e.g., a 3 mm diameter and an axial length of less than 1 mm). This ratio of the center section length to diameter (D1) may range from about 0:10 to 10:1, 0.1:6 to 2:1 and perhaps from 1:2 to 1:1.

[0124] As shown in Figures 9I-9K, control segments 252 may also be used to join and limit the expansion of the extension members 254 or the control segments may be placed elsewhere on the conduit to limit movement of certain features to a maximum dimension. By controlling the length of the control segments, the shape of the deployed conduit may be controlled. In the conduit shown in Figures 9I-9K, the conduit includes both center-control segments 256 and distal control segments 252. The center-control segments are arcuate shaped and join adjacent rib sections of the center section and the distal-control segments are arcuate and join adjacent distal extension members.

[0125] Figure 9J illustrates the conduit in a deployed configuration and shows the various control members straightening as the extension members and center section deploy. The proximal extension members, however, are not restricted by a control member and consequently may be deflected to a greater degree than the distal extension members. Accordingly, a conduit having control members connecting, for example, regions of the center section and having additional control segments connecting extension members, may precisely limit the maximum profile of a conduit when it is deployed. This, for example, is desirable when over-expansion of the conduit is hazardous or when the deployed profile must match, conform to, or affect the tissue that the conduit is being deployed into.

[0126] This also serves to control the deployed shape of the conduit by, for instance, forcing angle A1 to differ from angle A2. Using control segments in this manner can provide for cone-shaped conduits if the various types of control-segments have different lengths. For example, providing longer proximal-control segments than distal-control segments can make angle A1 larger than angle A2. Additionally, cylindrical-shaped conduits may be provided if the center-control segments and the extension-control segments are sized similarly such that angle A1 equals angle A2. Again, the control segments straighten as the conduit expands and the conduit is thus prevented from expanding past a predetermined amount.

[0127] The angles A1, A2 may vary and may range from, for example, 30 to 150 degrees, 45 to 135 degrees and perhaps from 30 to 90 degrees. Opposing members may thus form

angles A1 and A2 of less than 90 degrees when the conduit is deployed in a channel. For example, angles A1 and A2 may range from 30 to 60 degrees when the conduit is deployed. [0128] The control segments, as with other components of the conduit, may be added or mounted to the center section or alternatively, they may be integral with the center section. That is, the control segments may be part of the conduit rather than separately joined to the conduit with adhesives or welding, for example. The control segments may also be mounted exteriorly or interiorly to the members to be linked.

[0129] Figures 9L-9M illustrate another variation of a conduit **860** that includes deflecting extension members **856** at only one end of the conduit **860**. In this variation, the center section of the conduit may comprise a body portion **858**. The conduit **860** may have a covering **855** about a portion of the conduit **860**. The covering may extend throughout the length of the conduit **860** or it may be limited to a portion of the conduit **860**. As illustrated in Figure 9M, when expanded, the conduit **860** may form a reduced area **859** near the extension members **856**. The conduit cross section may be designed such that a diamond pattern is formed upon expansion of the conduit **860**, as illustrated in Figure 9M.

[0130] Figure 9N illustrates another variation of a conduit **862** having a first portion **864** and a second portion **866** and a passageway **868** extending therethrough. The first portion **864** may be a conduit design as described herein. In particular, the first portion **864** is configured to secure the conduit **862** to the airway wall **100**. The first portion **864** may or may not have a center that is expandable. The walls of the first portion **864** may be fluid-tight (either through design, or a fluid tight covering) to prevent tissue in-growth through the collateral channel. Alternatively, the first portion **864** may be partially fluid-tight to facilitate tissue in-growth to improve retention of the conduit **862** to the airway wall **100**. However, in the latter case, the first portion **864** should be designed to minimize tissue in-growth within the channel to prevent substantial interference with airflow through the conduit **864**. As with the first portion **864**, the walls of the second portion **866** of the conduit may or may not be fluid-tight. For example, the walls may be perforated or have openings through the side walls. If the second portion **866** is not fluid-tight, the larger area provides for improved airflow from lung tissue through the passageway **868** and into the airway. The second portion **866** may also be designed to be partially fluid-tight to encourage airflow through the conduit **862** but reduce the probability of blockage of the conduit **862**.

[0131] The second (or cage) portion may be relatively long. For example, the cage structure may have a length ranging from 2 to 20 mm and perhaps, from 6 to 15 mm. In one configuration, the cage has an axial length of 8-12 mm and a diameter larger than that of the center section when deployed and expanded. The cage diameter in this configuration may be 1.5-4 times the diameter of the center section. Again, the conduit may be formed as an integral tubular structure or it may be formed of a plurality of ribs or mesh components which are covered with a biocompatible material to prevent tissue ingrowth.

[0132] Figures 9O-9P illustrate another variation of a conduit 870. The conduit 870 may be formed from a tube that is slit to form extension members at a first portion 872 and second portion 876 with a center section 874 between the portions. The conduit 870 may be expanded as shown in Figure 9P such that the first 872 and second 876 portions maintain the center portion 874 in a collateral channel in an airway wall. The center section 874 may or may not be expandable.

[0133] Figure 9P illustrates the second portion 876 of the conduit 870 to expand in its center. The second portion thus has a basket or cage shape. The conduit 870, however, may be designed in other configurations as well (e.g., expanded to have a larger diameter at an end opposite to the center section 874.) The second portion 870 provides a large area in the lung tissue to permit a larger volume of air to pass from the lung tissue into the conduit 870. This design has an added benefit as the second portion 876 cannot be easily blocked by flaps of parenchymal tissue. A simple variation of the conduit 870 may be constructed from a metal tube, such as 316 stainless steel, titanium, titanium alloy, Nitinol, etc. Alternatively, the conduit may be formed from a rigid or elastomeric material.

[0134] Figure 10A illustrates another feature of the inventive conduit 200 of the present invention. As illustrated, this conduit 200 includes cage members 214 which have a length-increasing portion 244. The length-increasing portion 244 may be a section of the cage member 214 which forms a non-linear pattern. When desired, the non-linear pattern may be 'straightened-out' thus increasing the length of the cage member. In such cases, the non-linear pattern may eventually assume a linear pattern, or it may simply become straighter (i.e., substantially linear as compared to its original pattern or approach a linear pattern.) The length-increasing portion 244 may be formed in a sinusoidal pattern, an arc-shaped pattern, a parabolic pattern, a 'v-shaped' pattern, etc. It should be noted, that although the individual cage member may approach a non-linear pattern when viewed in

one plane (e.g., a top view), the cage member may still have a curve when viewed in another plane (e.g., a side view) such that it forms a cage with adjacent cage members.

[0135] One benefit of the length-increasing portion 244 may be observed during the expansion of the conduit 200. In some cases, a conduit 200 may compress or shrink in an axial direction as it radially expands. This axial shrinking may resist the expansion of the conduit 200 thereby causing a larger angle for retaining tissue between corresponding proximal 208 and distal 210 extension members. If this angle is too large the conduit 200 may not be securely placed. Also, in some cases, the axial shrinking may be a benefit because it may help to sandwich tissue between the proximal and distal extension members, further securing the conduit in place. The axial shrinking may occur when elongated ribs running axially bend to accommodate the conduit's radial expansion. As the ribs bend in one direction, the conduit tends to shrink in the axial direction unless, for example, a length increasing portion or other mechanism compensates for the axial shrinking.

[0136] As shown in Figure 10B, the use of length-increasing portions 244 permits the cage member 214 to increase in length as the cage expands, thereby allowing a smaller angle 246 to be formed between corresponding proximal 208 and distal 210 extension members. Moreover, the use of length-increasing portions 244 permits the overall conduit 200 to have a smaller axial length prior to deployment of the conduit 200 thus improving maneuverability of the conduit 200 during placement. It is not necessary for the length-increasing portion 244 to be found on each cage member 214, the invention also contemplates placement of the length-increasing portion 244 on less than all cage members 214.

[0137] Figures 10C-10D illustrate another conduit 200 having cage members 216 each of which has a length-increasing portion 236. The length-increasing portion 236 may be a section of the cage member 216 which forms a non-linear pattern. Unlike the cage members 214 discussed in figures 10A-10B, the cage members 216 of the conduit in Figures 10C-10D do not include control segments to limit the expansion.

[0138] Any variation of a conduit described herein may comprise a barrier layer which is impermeable to tissue. This aspect of the invention prevents tissue in-growth from occluding the collateral channel or passage of the conduit. The barrier layer may extend between the ends of the body or the barrier layer may extend over a single portion or discrete portions of the body of the conduit.

[0139] Figure 11 illustrates a cross section of an un-deployed conduit **200**. As discussed above, it may be desirable to prevent growth of tissue through, at least, the center section **202** of the conduit **200** once it is deployed. Accordingly, an inner covering **232** may be placed within the conduit **200** and adjacent to the center section **202**. The inner covering may be a tube (e.g., silicone, or other material) or a coating. In variations of the invention, the inner covering **232** may extend beyond the center section **202** and adjacent to the extension members **208**, **210**, or even into the cage **212**. Figure 11 also illustrates an outer covering **234** placed over the center section **202** of the conduit **200**. The outer covering **234** may be a tube, coating, etc. It may be comprised of silicone or other material. Furthermore, the invention is not limited to placing the outer covering **234** only on the center section **202** of the conduit **200**.

[0140] Another variation of the invention is illustrated in Figures 12A-12B. In this variation, a conduit contains a filler material between the openings of the ribs or mesh. For example, Figure 12A illustrates a partial plane view of a conduit **880** having a plurality of ribs or a mesh structure **882** as previously described. The conduit **880** includes placing a filler material **884** between each of the ribs/opening of the mesh. A covering **886** is then placed over the ribs/mesh **882** and filler material **884**. The covering **886** encapsulates the structure of the conduit **880** and covers the outer surface of the conduit **880** and the interior wall of the lumen or passageway of the conduit **880**. Figure 12B illustrates a partial sectional view of the conduit **880** of Figure 12A. Figure 12B illustrates the mesh **882** with filler material **884** adjacent to the mesh **882** and an outer covering **886** encapsulating the mesh **882** and filler material **884**. It is noted that the filler material **884** and covering **886** may be placed entirely throughout a conduit. Alternatively, the filler material **884** and covering **886** may be placed partially over a conduit as needed. It is believed that the addition of filler material to a conduit provides a uniform thickness of the covering which results in uniform and consistent stretching of the covering. Some various examples of filler material are, for example, wax, silicone, and urethane. The covering may consist of, for example, silicone, urethane, or similar materials.

[0141] Figures 13A-13C illustrate another variation of a conduit **888**. As shown in Figure 13A, the wall thickness of the material **896** between the extension members **890** and the center section **892** may be less than a thickness of the wall section of the material **896** at the center section **892**. As illustrated, if an outwardly radial force is applied to the extension members **890**, such a configuration results in bending at the area of reduced wall thickness

**894.** Consequently, and as illustrated in Figure 13B-13C, the extension members **890** expand in a predetermined manner. The material may be elastomeric and perhaps, urethane or silicone. Reduced thickness areas may also be used in metal frame conduits to encourage bending at pre-specified locations.

[0142] Figure 14A illustrates another variation of a conduit **200** having a tissue barrier **240**. The tissue barrier **240** prevents tissue ingrowth from occluding the collateral channel or passage of the conduit **200**. The tissue barrier **240** may coaxially cover the center section from one end to the other or it may only cover one or more regions of the conduit **200**. Thus, the tissue barrier may completely or partially cover the conduit. The tissue barrier **240** may be located about an exterior of the conduit's surface, about an interior of the conduit's surface, or the tissue barrier **240** may be located within openings in the wall of the conduit's surface as described above. Furthermore, in some variations of the invention, the center section **208** itself may provide an effective barrier to tissue ingrowth. The tissue barrier, of course, should not cover or block the entrance and exit of the passageway such that air is prevented from passing through the conduit's passageway. However, in some constructs, the tissue barrier may partially block the entrance or exit of the passageway so long as air may continue to pass through the conduit's passageway.

[0143] The tissue barrier may be formed from a material, or coating that is a polymer or an elastomer such as, for example, silicone, polyurethane, PET, PTFE, or expanded PTFE. Moreover, other biocompatible materials may be used, such as a thin foil of metal, alloy, etc. The coatings may be applied, for example, by either dip coating, molding, spin-coating, transfer molding, compression molding or liquid injection molding. Or, the tissue barrier may be a tube of a material and the tube is placed either over and/or within the conduit. The tissue barrier may then be bonded, crimped, heated, melted, fused or shrink fitted to the conduit. The tissue barrier may be tied to the conduit with a filament of, for example, a suture material. The tissue barrier may be placed on the conduit by either solvent swelling applications or by an extrusion process. Also, a tissue barrier may be applied by either wrapping a sheet of material about the conduit, or by placing a tube of the material about the conduit and securing the tube to the conduit. Likewise, a tissue barrier may be secured on the interior of the conduit by positioning a sheet or tube of material on the inside of the center section and securing the material therein.

[0144] Figures 14B and 14C respectively illustrate a side view and a front view of another conduit **300** having a partial tissue barrier coating. The conduit **300** includes a center

section **310**, a plurality of extension members **320**, and a partial tissue barrier **330**. The conduit **300** is thus different than that shown in Figure 14A in that the center section is longer and that the tissue barrier **330** only partially covers the extension members **320**. The center section **310** shown in figures 14B-14C is cylindrical or tubular-shaped. This shape may be advantageous when a relatively longer passageway is desired. Also, it is to be understood that the overall (or three dimensional) shape of the center section, when deployed, is not limited to the shape shown here. Rather, it may have various shapes such as, for example, rectangular, tubular, conical, hour-glass, hemi-toroidal, etc. Also, cage members may be connected to the center section or to the extension members. The barrier may cover the cage members as well. The cage members may be coaxially covered partially or completely by a tissue barrier.

[0145] Referring to Figures 14B-14C the tissue barrier **330** covers only a central region **350** of the extension members and leaves a free or end region **340** of the extension members uncovered. The end region **340** of the extension members **320** is shown as being open-framed. However, the invention is not so limited. The distal region of the extension members may be solid and it may include indentations, grooves, and recesses for tissue ingrowth. Also, the extension members may include small holes for tissue ingrowth. For example, the distal region of the extension members may have a dense array of small holes. In any event, the conduits described herein may include at least one region or surface which is susceptible to tissue ingrowth or is otherwise adherent to the tissue. Accordingly, tissue ingrowth at the distal region **340** of the extension members is facilitated while tissue growth into the passageway **325** is thwarted.

[0146] As shown in Figure 14D, tissue growth **360** into the uncovered region **340** further secures the extension members to the tissue wall **370**. The distal region of the extension members may also include tissue growth substances such as epithelial growth factors or agents to encourage tissue ingrowth. Accordingly, conduit **300** may be configured to engage the tissue wall **370** as well as to allow tissue to grow into predetermined regions of the conduit.

[0147] The conduit shown in Figure 14A also includes a visualization ring or marker **242**. The marker **242** is visually apparent during a procedure. The marker is observed as the conduit is placed in a collateral channel and, when the marker is even with the opening of the channel, the conduit may be deployed. In this manner, the visualization feature facilitates alignment and deployment of the conduits into collateral channels.



[0148] The visualization ring or mark may be a biocompatible polymer and have a color such as white. Also, the visualization feature may protrude from the center section or it may be an indentation(s). The visualization mark may also be a ring, groove or any other physical feature on the conduit. The visualization feature may be continuous or comprise discrete segments (e.g., dots or line segments).

[0149] The visualization feature may be made using a number of techniques. In one example, the mark is a ring formed of silicone and is white. The polymeric ring may be spun onto the tissue barrier. For example, a clear silicone barrier may be coated onto the conduit such that it coaxially covers the extension members and the center section as shown in Figure 14A. Next, a thin ring of white material such as a metal oxide suspended in clear silicone may be spun onto the silicone coating. Finally, another coating of clear silicone may be applied to coat the white layer. The conduit thus may include upwards of 1-3 layers including a tissue barrier, a visualization mark layer, and a clear outer covering.

[0150] The shape of the visualization mark is not limited to a thin ring. The visualization mark may be large, for example, and cover an entire half of the conduit as shown in Figure 14B (see reference numeral 384 of Figure 14B). The visualization mark may, for example, be a white, black, blue or another opaque coating disposed on the proximal or distal half of the conduit. The visualization mark thus may extend from an end of the extension members to the center section of the conduit. As explained in more detail below, when such a device is deposited into a channel created in lung tissue, the physician may observe when one-half of the conduit extends into the channel. This allows the physician to properly actuate or deploy the conduit to secure the conduit in the tissue wall.

[0151] The visualization feature is made visually apparent for use with, for example, an endoscope. The visualization feature, however, may also be made of other vision-enhancing materials such as radio-opaque metals used in x-ray detection. It is also contemplated that other elements of the conduit can include visualization features such as but not limited to the extension members, cage members, tissue barrier, control segments, etc.

[0152] The conduits described herein may include modified surfaces that prevent the channel from closing by reducing tissue growth into the passageway. The modified surfaces may also prevent the conduit from being ejected from the channel as the wound heals. The surfaces of the conduit may be modified, for example, by depositing a bioactive substance or medicine onto the exterior surface of the conduit.

[0153] The bioactive substances are intended to interact with the tissue of the surgically created channels. These substances may interact with the tissue in a number of ways. They may, for example, accelerate wound healing such that the tissue grows around the exterior surface of the conduit and then stops growing; encourage growth of the epithelial or endothelial cells; inhibit wound healing such that the injury site (e.g., the channel or opening) does not heal leaving the injury site open; and/or inhibit infection (e.g., reduce bacteria) such that excessive wound healing does not occur which may lead to excessive tissue growth at the channel thereby blocking the passageway. However, the foregoing statements are not intended to limit the present invention and there may be other explanations why certain bioactive substances have various therapeutic uses in the lung tissue. Again, the bioactive substances are intended to prevent the implant from being ejected as well as prevent the lung tissue from filling or otherwise blocking the passageway of the conduit.

[0154] A variety of bioactive substances may be used with the devices described herein. Examples of bioactive substances include, but are not limited to, pyrolytic carbon, titanium-nitride-oxide, paclitaxel, fibrinogen, collagen, thrombin, phosphorylcholine, heparin, rapamycin, radioactive  $^{188}\text{Re}$  and  $^{32}\text{P}$ , silver nitrate, dactinomycin, sirolimus, cell adhesion peptide. Again, other substances may be used with the conduits such as those substances which affect the wound healing response (or rate) of injured tissue or which affect any physiological, biological, or mechanical characteristic of tissue such as tissue modulus or elasticity, cell regeneration rate, smooth muscle contractibility, etc.

[0155] A cross section of a conduit 300 having a modified surface is shown in Figure 14E. In particular, the conduit 300 comprises an inner frame layer or ribs 380 which define a passageway 381 for air to flow through. Coaxially surrounding the frame 380 is a tissue barrier 330. Additionally a visualization coating 384 is disposed on a portion of the tissue barrier 330. The visualization coating 384 is deposited as described above. A bioactive substance 386 may be deposited on one or both the visualization and tissue barrier layers either directly or via a binding layer as described below. In this manner, the bioactive substance is disposed on an exterior surface of the conduit and contacts tissue when the device is deployed in a channel. However, it is contemplated that additional layers may be added such as, for example, an additional silicone layer over the visualization layer. Typically, the bioactive layer will form the outer-most layer.

[0156] Also the order of the layers may be different than that described above. For example, the visualization layer may be disposed over the bioactive layer. Also, not all coatings and materials shown in Figure 14E are necessary to carry out the present invention. For instance, the bioactive substances in some cases may be deposited directly on the open-frame 380.

[0157] The bioactive layer may also serve as the visualization coating or tissue barrier in some instances. For example, silicone and one or more bioactive substances may be mixed together and disposed on the conduit as a single coating. The single integral layer may serve both to physically and chemically prevent tissue from filling the conduit's passageway. It may also be visually apparent during a procedure.

[0158] Additionally, the bioactive substances may be deposited on the exterior surface of the conduit evenly or in discrete (intermittent) amounts. The thickness of the coatings may be uniform or the thickness may vary across certain regions of the conduit. This may provide higher therapeutic doses corresponding to certain regions of the injury site. For example, it may be desirable to provide a higher concentration of a bioactive substance near the ends of the conduit rather than in the center section.

[0159] The bioactive coatings may be selectively applied by spraying the bioactive substance onto uncovered regions of the conduit. For example, the bioactive substances may be disposed on at least a portion of the tissue barrier or the open-frame (or mesh) structure itself. The substances may also be applied by dipping, painting, printing, and any other method for depositing a substance onto the conduit surface. Additionally, binding materials may be applied to the exterior surface of the conduit upon which the bioactive agents may be deposited. Cross-linked polymers and or biodegradable polymers such as, for example, chondroitin sulfate, collagen and gelatin may be applied to the exterior surface of the conduit prior to depositing the bioactive substances. Additionally, the exterior surface of the conduit may be treated via etching processes or with electrical charge to encourage binding of the bioactive substances to the conduit.

[0160] Again, the bioactive substances may be deposited on the exterior of the conduits to prevent ejection of the conduit from the injury site. The bioactive substances serve to reduce or impede tissue growth into the conduit's passageway. In this manner, the conduits maintain the patency of channels surgically created in the lung airways allowing air to pass therethrough.

[0161] Figures 14F-14I illustrate a variation of a conduit 200 having membrane-supports 215. The membrane-supports serve to prevent the tissue barrier from tearing between the extension members 208, 210.

[0162] Figures 14F and 14G show the conduit 200 without a tissue barrier to better illustrate the frame of the conduit. In particular, Figure 14F shows a planar projection of a conduit 200 in an undeployed state. Figure 14G shows a side view of the conduit 200 in an undeployed state.

[0163] Figures 14H and 14I illustrate the conduit 200 in a deployed state. In particular, Figure 14H is a side view of the conduit 200 in a deployed state and Figure 14I shows a front view of the conduit shown in Figure 14H. As shown, membrane-supports 215 straighten when the extension members 208, 210 are rotated into a deployed configuration. The membrane-supports 215 support the tissue barrier 240 between the extension members as the tissue barrier is stretched between the extension members during deployment. Accordingly, the membrane-supports serve to prevent tearing of the tissue barrier during deployment of the conduit 200. These membrane-supports may be incorporated into other designs described herein. The membrane-supports are connected or otherwise formed between the extension members or cage members. More particularly, the membrane-supports may be positioned at or near the ends of the coating or tissue barrier. The membrane-supports may also extend from the ends of the extension members or cage members and connect adjacent members together. In this manner, and when the conduit is coated with a tissue barrier, the membrane-supports form a bridge across deployed extension members and cage members preventing tearing of the tissue barrier.

[0164] In contrast to diameter-control members described above, membrane-support members may not act to control the shape of the conduit and may remain substantially curved or non-straight upon deployment. Again, the membrane-support members can provide a bridge across the deployed extension members preventing tearing of the tissue barrier.

[0165] Figures 14J and 14K illustrate another conduit 200 having features which serve to prevent tearing of the tissue barrier during deployment of the conduit. In particular, the conduit 200 includes tapered extension members 208, 210 which, because of their reduced profile as compared to untapered extension members, allow more (and perhaps thicker) tissue barrier material to occupy the space between the extension members. When the extension members are deployed as shown in Figure 14K, the tissue barrier 240 stretches

from one extension member to the next. The tissue barrier may be less likely to tear between the deployed extension members due to the increased amount of tissue barrier material between the extension members as compared to conduits which have full size, untapered extension members. Tapered extension members or tapered petals may be incorporated into other conduit designs described herein. Also, cage members may have tapered ends to reduce tearing between the cage members when the conduit is deployed.

[0166] Figures 15A-15F illustrate another variation of a conduit **200**. Figure 15A provides a perspective view of a conduit **200** after deployment. The conduit **200** includes proximal extension members **202** and cage members **216** on either side of a center section **208**. In this variation, a portion of the cage members **216** located between the fixed end **218** and the intermediate segment **222** is adapted to assume a position substantially transverse to the passage. In such a case, the portion serves a similar function as the proximal extension members **202** in that tissue is retained between the cage members **216** and the proximal extension members **202** thereby retaining the conduit **200** within an airway wall. As illustrated in the figure, the remainder of the cage member **216** may form a cage structure **224**.

[0167] Figure 15A also illustrates the inventive conduit **200** as having a tissue barrier **226** located about the center section **208** of the conduit **200**. Variations of the inventive conduit may include such a tissue barrier **226** to prevent tissue in-growth from occluding the collateral channel or passage of the conduit **200**. The tissue barrier **226** may extend between the ends of the center section **208** or it may cover various portions of the conduit **200**.

[0168] Figure 15B illustrates a cross-sectional view of the conduit **200** of Figure 15A. As illustrated, the tissue barrier **226** is located about an exterior of the center section **208** of the conduit **200**. However, the invention is not limited as such, for example the tissue barrier **226** may be located about an interior of the center section, or the barrier **226** may be located within an opening of the center section. Furthermore, in some variations of the invention, the center section **208** itself may provide an effective barrier to tissue in-growth.

[0169] Figures 15C and 15D illustrate a cylindrical projection view of the conduit **200** of Figure 15A without a tissue barrier. These planar views show the conduit **200** in a flat and "un-rolled" state for purposes of illustration. Figure 15C illustrates the conduit **200** prior to deployment. The members comprising the center section **208** are in close proximity, thus allowing the center section **208** to assume a smaller profile during, for example, delivery to

an implant site. Figure 15D illustrates the conduit **200** after expansion of the center section **208** and proximal members **202**.

[0170] Figures 15E and 15F illustrate a side view of the conduit **200** of Figure 15A prior to deployment of the proximal extension members **202** and cage members **216**. For purposes of illustration, the conduit **200** is shown without a tissue barrier. Figure 15E shows the center section **208** in a reduced profile state. Figure 15F shows the center section **208** in an expanded profile state (as compared to Figure 15E). Figure 15F also illustrates a variation of the invention where the proximal extension members **202** expand as the center section **208** expands.

[0171] Accordingly, the conduits **200** of the present invention may have center sections that are expanded into a larger profile from a reduced profile, or, the center sections may be restrained in a reduced profile, and upon release of the restraint, return to an expanded profile. The conduits of the present invention may be comprised from, for example, a shape-memory alloy, a super-elastic alloy, stainless steel, titanium, titanium alloy, nitinol, MP35N (a nickel-cobalt-chromium-molybdenum alloy), polymers, any implantable material etc.

[0172] Figure 16A illustrates a planar view of another variation of a conduit **200**. The conduit **200** comprises a center section **208** having proximal extension members **202** and cage members **216** on either end of the center section **208**. As noted throughout this disclosure, the number of extension members **202**, **216** may vary as required. In this illustration, the movable or free ends of both the proximal extension members **202** and the cage members **216** include proximal control segments **232** and cage control segments **234** respectively. The control segments **232**, **234** may connect at least two extension members to control expansion and/or formation of the extension members upon deployment of the conduit **200**. As described herein, upon deployment, the proximal extension members **202** and cage members **216** may rotate about the center section **202**. The proximal control segments **232** and cage control segments **234** may limit the extent to which the extension members **202**, **216** rotate, or prevent them from over-expanding, etc. The control segments **232**, **234** may also assist the conduit **200** in assuming a desired shape and for maintaining structural rigidity of the conduit **200** when implanted. Although the control segments **232**, **234** are illustrated as being on the ends of the extension members **202**, **216**, the invention is not limited as such. For instance, the control segments **232**, **234** may be placed anywhere

along the extension members **202**, **216**. The control segments may also be placed at the center section to limit the expansion of the center section as described above.

[0173] Figure 16B illustrates the control segments **234** located on the cage members **216** assisting in formation of the cage **224**. The control segments **234** may control the diameter of a portion of the cage **224** during expansion and/or prevention of over-expansion of the portion of the cage **224**. In the variation of the invention depicted in Figure 16B, the control segments **234** cause an end of the cage structure **224** to form a smaller profile than a center of the cage structure **224**. It is noted that various other configurations are considered to be within the scope of this invention. Figure 16B also illustrates how the proximal control segments **232** control expansion and rotation of the respective extension members.

[0174] It is noted that the invention is not limited to having control segments **232**, **234** on each extension member **202**, **216** of the conduit **200**. Instead, the control segments **232**, **234** may be found on one or more extension members **202**, **216** of the conduit **200**. Moreover, more than one control segment may be attached to the extension members.

[0175] Figure 16C illustrates another conduit **200** having proximal extension members **202**, a center section **208**, and a plurality of basket or cage members **216**. The cage members are shown joined with segments **234**. The conduit **200** shown in Figure 16C also includes center-control segments **235** to control and limit the expansion of the center section when deployed. In this case, the center-control segment is arcuate or circular-shaped. However, the center-control segments may vary. For example, the center-control segment may have a semi-circular, "V", or other-type of shape which provides for limited expansion. Further, the center-control segments may connect one or more of the center section members together. Also, the center-control segments may connect adjacent or non-adjacent center section members. The center-control segments may further be doubled up or reinforced with ancillary control segments to provide added control over the expansion of the center section. The ancillary control segments may be different or identical to the primary control segments.

[0176] Figure 16D illustrates the conduit **200** in its deployed configuration. When deployed, the center-control segments **235** bend into another configuration. The center-control segments **235** shown in Figure 16D are deformed to a diamond shape as each curved (or arcuate) segment straightens. However, as discussed above, the invention is not so limited and includes other configurations of center-control segments.

[0177] Figure 16E shows another conduit having a tissue barrier **240** and a visualization ring **242**. The tissue barrier **240** covers center section **208** and prevents tissue in-growth into the conduit. The tissue barrier **240** shown in Figure 16E also covers the proximal extension members **202** and a portion of cage member **216**. The tissue barrier may be a biocompatible polymer as described herein and prevents tissue and mucous from closing or blocking the passage of the conduit. While the tissue barrier is shown covering all of the proximal extension members, the invention is not so limited. The tissue barrier may cover more or less of the conduit so long as it does not prevent air from passing through the passage.

[0178] The conduit shown in Figure 16E also includes a visualization ring or marker **242**. The visualization marker may be similar to that described above. The visualization feature may be added to the conduit using various materials including, but not limited to, biocompatible inks, paints, epoxy, metals, metal oxides, alloys, polymers or combinations thereof. An ink pen, for example, may be used to draw a visualization feature onto the conduit. Also, a material may be wrapped around the conduit or embedded in a tissue barrier to form the visualization feature. Additionally, the visualization feature may be made of other detectable materials such as radio-opaque metals used in x-ray detection.

[0179] Accordingly, the visualization feature of the present invention may be added to the center section of the conduit and perhaps to the tissue barrier surrounding the center section to facilitate visualization and deployment of the conduit. It is also contemplated that other elements of the conduit can include visualization features such as but not limited to the extension members, tissue barrier, control segments, etc.

[0180] The conduit shown in Figures 16C-16E is fabricated, used and deployed similar to the conduits described herein. Also, aspects of the conduit **200** shown in Figures 16C-16E (e.g., the visualization ring or the control segments) may be used in combination with other examples set forth in this description except, of course, where features are mutually exclusive.

[0181] Figure 17A illustrates another variation of a conduit **200**. In this variation, the conduit **200** comprises a tube having a pattern which forms the extension members **202**, **216**, **228** and center section **208**. Figure 17A illustrates the conduit **200** in a pre-deployed configuration. Figure 17B illustrates the conduit **200** after deployment. As illustrated, the proximal extension members **202** rotate about the center section **208**. This variation illustrates a conduit **200** having both cage members **216** and distal extension members **228**



on a distal end **212** of the center section **208**. The distal extension members **228** are similar to the proximal extension members **202** in that they rotate about the distal end **212** of the center section. After rotation, proximal extension members **202** along with the distal extension members **228** assist in retaining the conduit **200** within the airway walls as tissue is located between the extension members **202**, **228**. The cage members **216** assume a cage structure **224** adjacent to a distal end of the passage of the conduit **200**. As discussed above, the cage structure **224** formed by the cage members **216** provides a large area in the lung tissue to permit a larger volume of air to pass from the lung tissue into the conduit and also prevents parenchymal (or other) tissue from preventing air from passing through the conduit passage.

[0182] Figure 17C illustrates a front view taken along the line 17C-17C of Figure 17B. As illustrated, the cage members **216** move inwards to form the cage structure **224** over the passageway while the extension members **228** move in the opposite direction. In variations of the invention, the cage members **216** may move inwards sufficiently so that one or more of the cage members **216** touches. Similar to other conduits described herein, deployment of the conduits depicted in Figures 17A-17C may be accomplished, for example: via use of a pre-configured conduit that is restrained in a pre-deployment shape whereupon release of the restraints causes deployment; or a shape memory alloy capable of returning to a deployed shape upon reaching a certain temperature.

[0183] Figures 17D-17E illustrate a variation of the inventive conduit **200** similar to that shown in Figures 17A-17C. However, rather than being constructed from a tube structure, this variation comprises a frame, wire or mesh structure.

[0184] Figure 17D illustrates an expanded planar view of the conduit **200** having both cage members **216** and distal extension members **228** on a distal end of the center section **208**. The proximal end of the center section **208** includes a plurality of proximal extension member **202**.

[0185] Figure 17E illustrates a front view (from the distal to proximal end) of the conduit **200**. As illustrated, the cage members **216** move inwards to form a cage structure **224** over the passageway while the extension members **228** move in the opposite direction. In variations of the invention, the cage members **216** may move inwards sufficiently so that one or more of the cage members **216** touches. As mentioned herein deployment of this conduit may be accomplished, for example: via use of a pre-configured conduit that is restrained in a pre-deployment shape whereupon release of the restraints causes

deployment; or a shape memory alloy capable of returning to a deployed shape upon reaching a certain temperature. Moreover, as shown in Figure 17E and for reasons described herein, the conduit **200** may also have a tissue barrier **226** located at the center section **208** of the conduit.

[0186] Figure 17F illustrates another variation of a conduit **200**. In this variation, the free ends of the cage members **216** are connected to form the cage structure **224** and the fixed ends of the cage members **216** extend to form the center section **208** of the conduit **200**. The proximal extension members **202** are formed from the opposing end of the center section **208**. The extension members and the center section of this variation of conduit may be formed from one or more wires or similar stock material. As illustrated, a tissue barrier **226** is placed over the center section **208**. As discussed herein, the invention contemplates forming the tissue barrier **226** from an elastic material that expands upon deployment of the conduit **200**.

[0187] Figure 18A illustrates a method for deployment of a conduit **200**. First, a delivery device **300** is pre-loaded with a conduit **200**. An access device **304** (e.g., an endoscope, a bronchoscope, or other device) may optionally be used to place the delivery device **300** adjacent to a collateral channel **112**.

[0188] As the delivery device **300** approaches the collateral channel **112** a guide wire **302** may be used to place the delivery device **300** into the collateral channel **112**. The guide wire **302** may be a conventional guide-wire or may simply be comprised of a super-elastic material. The use of a guide wire is optional as the invention contemplates placement of the conduit **200** using only the delivery device **300**.

[0189] Figure 18B illustrates the delivery device **300** after it is advanced through the collateral channel **112**. As illustrated, if a guide wire **302** is used, it may be withdrawn from the site. Figure 18B also illustrates articulation (or bending) of the deliver device **300** to access the collateral channel **112**. However, the invention also contemplates that the access device **304** may be articulated to position the delivery device **300** such that it may advance through the collateral channel **112**. In such a case, the delivery device **300** may exit straight from the access device **304**. In such cases, the delivery device **300** may or may not articulate within the access device **304**.

[0190] Figure 18C illustrates deployment of the conduit **200**. As illustrated, the conduit **200** may be pre-loaded on the delivery device **300** such that the conduit **200** is restrained about an inner shaft/catheter **306** by outer tubular members **308**, **310**. As described herein,

the conduit **200** may be comprised of an elastic or super-elastic material which is restrained in a reduced profile for deployment. Upon release of the restraints, the conduit **200** assumes a deployed shape. Figure 18C shows a variation of the invention where the outer tubular members **308**, **310** are in a telescoping arrangement. In such a case, the inner catheter **306** is advanced moving the first outer tubular member **308** and the conduit **200** distally relative to the second tubular member **310**. As shown by the arrows, release of the proximal extension members **202** from the restraint causes the proximal extension members **202** to rotate about the center section of the conduit **200** to engage the airway wall **110**.

[0191] Figure 18D illustrates the next step as the inner catheter **306** and first outer tubular member **308** are again advanced. However, the proximal extension members **202** of the conduit **200** prevent the conduit **200** from advancing. The relative movement of the first outer tubular member **308** to the conduit **200** releases the cage members **216** of the conduit **200**. As a result, the cage members **216** form a cage structure upon their release from the first outer tubular member **308**. As illustrated in Figure 18D, in some variations of the invention, once the conduit **200** is no longer restrained, the conduit's center section **208** may expand to assume a deployed state or profile.

[0192] Figure 18E illustrates the deployed conduit **200** once the delivery device **300** is removed from the site. In this variation of the invention, the conduit **200** contains cage members **216** where the cage members include a portion **230** that is adapted to assume a position substantially transverse to the passage. Accordingly, this portion **230** of the cage member **216** functions to maintain the conduit **200** within the airway wall **110** in a manner similar to the proximal extension members **202**.

[0193] Figure 18F illustrates another deployed conduit having a cage **216**, a tissue barrier **240** and a marker **242**. The proximal extension members are covered by the tissue barrier. The conduit **200** shown in this figure may be deployed when the marker **242** is aligned with the channel opening. The marker is conspicuous and thus its position is readily ascertainable via an endoscope or other vision instrument.

[0194] Accordingly, the inventive conduit described herein may be formed of a plastically deformable material such that the conduit is expanded and plastically deforms into a deployed configuration. The conduit could also comprise a shape memory alloy that, upon reaching a particular temperature (e.g., 98.5 °F) assumes the deployed configuration. Moreover, the conduit may be constructed to have a deployed configuration, but is elastic such that it may be restrained in a pre-deployed configuration. As such, removal of the

restraints causes the conduit to assume the deployed configuration. A conduit of this type could be, but is not limited to being, comprised from a shape memory alloy or a thermoplastic elastomer.

[0195] The conduits of this invention may be formed from a tube that is cut to form the extension members, center section, and cage portion. Alternatively, the conduit may be formed from a cylinder with the passageway being formed through the conduit. The conduit may also be formed from a sheet of material in which a specific pattern is cut. The cut sheet may then be rolled and formed into a tube.

[0196] The conduits described herein may be comprised of a metallic alloy material (e.g., stainless steel, 316 stainless steel, titanium, titanium alloy, MP35N, etc.), a shape memory alloy, a super-elastic alloy (e.g., a NiTi alloy), a shape memory polymer, a polymeric material, a material with rigid properties, a material with elastomeric properties, or a combination thereof. The conduit may be designed such that its natural state is an expanded state and it is restrained into a reduced profile, or, the conduit may be expanded into its expanded state by a variety of devices (e.g., a balloon catheter.) The conduit described herein may be manufactured by a variety of manufacturing processes including but not limited to laser cutting, chemical etching, punching, stamping, etc.

[0197] As mentioned above, the number of and cross sectional area of the extension members on a conduit may be selected as needed for the particular application. Also, the extension members may bend/pivot in such a way that they anchor into the tissue thereby securing placement of the conduit. Or, the extension members or the center section may contain barbs or other similar configurations to better adhere to the tissue. Moreover, the orientation of the extension members may vary as well. For example, the extension members may be configured to be radially expanding from the center section, or they may be angled with respect to a central axis of the conduit.

[0198] Figures 19A-19C illustrate deployment of a conduit 200. Figure 19A illustrates a conduit placed on a delivery device 302, with an outer sheath 304 covering a portion of the conduit 200. The delivery device 302 and the outer sheath 304 direct the conduit 200 to a site of a collateral channel which, as described above, is an opening in an airway wall 110. An endoscope, bronchoscope, or similar device may be used to direct the delivery device, sheath, and conduit to the site. In such a case, the delivery device is usually advanced through the working channel of the bronchoscope/endoscope. Upon advancement of the conduit 200 to the site, the cage 212 end of the conduit 200 (this end also being referred to

as the “parenchymal side”) is inserted through the airway wall **110** and into the parenchymal tissue of the lung. In most cases, the center section **202** of the conduit **200** remains in the collateral channel and is surrounded by the airway wall **110**. As described elsewhere, the center section **202** of the conduit **200** may have a covering or other means to prevent tissue growth through the conduit **212** and into the conduit passage.

[0199] Figure 19B illustrates withdrawal of the outer sheath **304** from the conduit **200** after the conduit **200** is suitably positioned in the tissue. As the outer sheath **304** is withdrawn, distal extension members **210** rotate about the center section **202** of the conduit **200**. The distal extension members **210** may automatically deploy without external means. For example, the conduit **200** may be comprised of a shape memory alloy, or, the extension members may be resiliently biased to expand, etc. Alternatively, the distal extension members **210** may be rotated by means of a balloon, or similar actuation means, or application of current may cause the extension member **210** to assume the deployed position. In any case, once the distal extension members **210** deploy, the extension members prevent migration of the conduit **200** into the airway.

[0200] Figure 19C illustrates deployment of the proximal extension members **208**. Like the distal extension members **210**, the proximal extension members **208** may deploy automatically, or they may be actively deployed. For example, Figure 19C illustrates a proximal extension member **208** rotating about the center section **202** of the conduit **200**. As shown, the proximal extension members **208** work in conjunction with the distal extension members **210** to retain the airway walls therebetween. As a result, the conduit is unable to migrate out of the airway wall **110**. Figure 19C also demonstrates how placement of the cage **212** or parenchymal end of the conduit **200** within the parenchyma provides a structure facilitating the improved release of trapped gasses from a hyper-inflated lung.

[0201] It is noted that the variation of the conduit depicted in Figures 19A-19C is rounded and closed at the distal end of the cage **212**. As such, it is not necessary that the passage of the conduit **200** extends throughout the entire conduit **200**. All that is required is that the passage extend through to the cage **212** of the conduit such that trapped air may pass through the cage **212** and along through the conduit.

[0202] It is further noted in Figures 19A-19C that the illustrated conduit **200** is a variation where the center section **202** of the conduit **200** includes openings once the distal extension members **210** rotate from the conduit **200**. As discussed above and as illustrated in Figures 19B and 19C, the distal extension members **210** may rotate sufficiently such that

the portion of the center section **202** with openings is positioned outside of the airway wall **110**. However, the invention is not necessarily limited as such.

[0203] Figures 20A-20B illustrate deployment of another variation of a conduit **200**. Figure 20A illustrates the conduit **200** after placement within an airway wall **110** and after deployment of the distal extension members **210**. As seen in Figure 20A, the conduit **200** includes a cage **212** having cage members **214** which are attached to a free (or movable) end of the distal extension member **210**. Accordingly, as the distal extension members **210** rotate about the center section **202** of the conduit **200**, the extension members **210** also expand a portion of the cage **212** into an expanded state.

[0204] Figure 20B illustrates the conduit of Figure 20A after deployment of proximal extension members **208**. As shown in Figure 20B, the proximal and distal extensions **208**, **210** prevent the conduit **200** from migrating from its deployment site within the airway wall **110**. Furthermore, the expanded cage **212** having openings **220** therein, provides an expanded structure facilitating the improved release of trapped gasses from a hyper-inflated lung.

[0205] Figures 21A-21C illustrate another way to deploy a conduit **200** using a balloon catheter **310**. The balloon catheter **310** will have an expandable balloon **314** at a distal end. The conduit **200** will be placed over the balloon section **314**. The conduit **200** shown in Figures 21A-21C is for illustration purposes only. As such, features of the conduit (e.g., openings, outer coverings, etc.) are omitted for the sake of clarity. An outer sheath **312** may be used to advance the balloon catheter **310** and conduit **200** to the desired site within the airways. It is noted that the delivery device shown in Figure 21A may also have another lumen which permits advancement of a guide wire (not shown) to assist in location of the collateral channel and placement of a conduit within the channel (see below). The balloon catheter **310** may also have an axial member **316** (e.g., wire, rod, etc.) that is fixedly attached to a distal end **318** of the balloon catheter **310**. As indicated in the figure, the assembly will be advanced through an airway wall **110**.

[0206] Figure 21B illustrates deployment of the conduit **200**. As illustrated, the balloon **314** includes first, second, and third portions where the first and third portions expand to a greater diameter than the second portion. This expansion of the balloon **314** forces the proximal and distal extension members **208**, **210** to rotate about a center section **202** of the conduit **200**. This variation of the conduit **200** also includes a cage **212** that achieves an expanded state as a result of inflation of the balloon **314**. However, for conduit variations

not having an expandable cage, a balloon may be adapted to deploy the proximal and distal extension members only. Although not illustrated, it is also contemplated that the inventive conduits may be deployed with a balloon catheter that includes one or more balloon portions that do not expand to different sizes. In such a case, the conduit may be adapted to assume a pre-designed deployed shape upon expansion of the balloon catheter. Accordingly, the pre-designed shape of the conduit rather than a balloon catheter may dictate the shape of the conduit after deployment.

[0207] Figure 21B also illustrates the axial member 316 pulling the distal end 318 of the balloon catheter 310 in a proximal direction as indicated by the arrow. Such an action may further assist in the deployment of the conduit 200 as the balloon 314 compresses in an axial/longitudinal direction. The balloon catheter shaft 311 or the outer sheath 312 may assist in compression of the balloon 314 as the pulling of the distal end 318 against the balloon catheter shaft 311 or the outer sheath 312 further compresses the balloon 314.

[0208] When the conduit 200 is sufficiently deployed, the axial member 316 can be pushed to facilitate straightening or stretching of the balloon 314 in an axial/longitudinal direction which further eases removal of the balloon catheter 310 from the conduit 200.

[0209] Figure 21C illustrates conduit 200 deployed about an airway wall 110. As discussed throughout this disclosure, the proximal and distal extension members 208, 210 retain the conduit 200 in the airway wall. Then, the balloon catheter 310 may be withdrawn into the outer sheath 312 and both the catheter 310 and sheath 312 are withdrawn from the site leaving the conduit 200 in place. The balloon 314 may serve several functions. As discussed above, the balloon 314 can expand to rotate the extension members 208, 210. Moreover, the balloon 314 may also serve to center the conduit 200 within the collateral channel, as it simultaneously begins to expand the conduit 200 thereby securing the conduit 200 within the collateral channel.

[0210] Figure 21D illustrates another variation of a balloon having two layers of balloon material. The first balloon layer 314 provides increased burst strength against the pressurized fluid in the balloon and may or may not be elastomeric. The second balloon layer 315 may be elastomeric and may protect the first balloon from the edges of the conduit 200 during inflation of the balloon, and/or may assist in returning the first balloon layer 314 to a compressed state when the first balloon layer 314 deflates to ease removal of the catheter from the conduit 200.

[0211] The design of the balloon may be designed as needed to impart the desired angle to the extension members of the conduit. The balloons described herein may be constructed of polyethylene terephthalate (PET), nylon, or another material which is used in constructing inflatable members such as the balloon members used in balloon catheters.

[0212] It should be noted that deployment of conduits of the present invention is not limited to that shown above, instead, other means may be used to deploy the conduits. Other means for deployment of the conduits of the present invention include, but are not limited to, mechanical wedges, lever-type devices, scissors-jack devices, open chest surgical placement, etc.

[0213] A balloon catheter can be used to deploy conduits made from materials that lack shape memory properties. That is to say, in some cases, a balloon catheter can deploy conduits that are inelastic or plastically deformable. Additionally, when using a balloon catheter to deploy the conduit, the balloon member itself may be made of an elastic or inelastic material. The balloon member may also have various shapes or profiles including but not limited to cylindrical, spherical and hourglass shapes. The balloon may be elastic or inelastic. An inelastic cylindrical balloon, for example, can be used to deploy conduits which have diametrically or otherwise controlled shapes. Again, as described above, the conduits of the present invention may include control segments which limit the shape of the conduit to a maximum or certain deployed shape. However, in conduits that lack control members or in conduits that are otherwise not inherently shape restricted, the balloon member can impose its shape onto the conduit when the balloon member is expanded. For example, an hourglass-shaped balloon may impose an hourglass shape onto a shapeable conduit thereby securing the conduit in a channel.

[0214] It is contemplated that conduits may be attached to a delivery device using the natural resiliency of the conduit, or, in those cases where the conduit is spring loaded, the conduit may be restrained in a reduced profile and may be removably affixed to the delivery device using an adhesive, or a removable sleeve such as a heat shrink tube. In such cases, expansion of the conduit using, for example, balloon causes release of the conduit by release of the adhesive or breaking of the heat shrink tubing. The means of attachment may be bioabsorbable and remain in the body, or may remain affixed to a delivery device and is removed upon removal of the delivery device.

[0215] Another method of deploying a conduit includes restraining the conduit about a delivery device using a wire or string tied in a slip-knot or a series of slip-knots. When the



conduit is delivered to a desired location, the proximal end of the wire or string may be pulled which releases the wire/string and deploys the conduit.

[0216] Figures 22A-22D illustrate a method for deploying a conduit 200. As illustrated in Figure 22A, a conduit 200 is placed onto a deployment catheter 332. The deployment catheter 332 may comprise a sheath 334 and a shaft 336. The shaft 336 may contain cap portions 338. In such a case, prior to deployment, the conduit 200 may be loaded on the shaft 336 between the sheath 334 and cap portions 338. For example, the proximal extension members 208 may be placed adjacent to the sheath 334 while the cage 212 is placed against the cap portions 338. In some variations of the invention, one or more of the cap portions 338 may have a lip 340 which retains the conduit cage 212. It is contemplated that a conduit 200 may be delivered to a user pre-loaded on the catheter 332 in such a pre-deployed configuration.

[0217] Figure 22B illustrates expansion of the cage 212 by moving shaft 336 relative to the sheath 334 as shown by the arrow. In this way, the conduit 200 compresses between the sheath 334 and the cap portions 338. Compression of the conduit 200 causes the proximal and distal extension members 208, 210 to rotate and move away from the shaft 336. In the conduit 200 variation depicted in Figure 22B, the conduit 200 includes cage members 214 which follow the free end of the distal extension member 210 and move away from the shaft 336 to form the expanded cage.

[0218] Moreover, the invention may include a deployment catheter that is configured to be easily removed from the deployed conduit 200. For example, the cap portions 338 of the shaft 336 may be spring biased to remain together. In such a case the cap portions 338 of the shaft 336 will have a natural state where the cap portions 338 remain immediately adjacent to one another. Given this configuration, when the cap portions 338 are attached to the conduit 200, as shown in Figure 22B, the conduit 200 prevents the cap portions 338 from returning to their natural state. As discussed above, the cap portions 338 may have a lip 340 which assists securing the cap portions 338 on the conduit 200. As shown in Figure 22C, movement of the shaft 336 in a distal direction (as indicated by the arrows), permits disengagement of the lip 340 of the cap portions 338 from the conduit 200. This action permits the cap portions 338 to close together.

[0219] As illustrated in Figure 22D, once the cap portions 338 return to their natural state, the conduit 200 and shaft 336 may be de-coupled. Decoupling of the conduit 200 and shaft

**336** may be achieved by, for example, withdrawal of the shaft **336** from the conduit, or, use of the sheath **334** to advance the conduit **200** over the shaft **336** and cap portions **338**.

[0220] Figures 23A-23C illustrate placement of a conduit via use of a guide-member. Figure 23A illustrates directing a guide-member, such as a guide-wire **320**, or other similar device into a collateral channel **112**.

[0221] Figure 23B illustrates the advancement of a catheter device **322** into the collateral channel **112**. The catheter **322** may advance over the guide-member **320** and into the collateral channel **112**. As discussed above, the conduit **200** is then deployed in the collateral channel **112**.

[0222] Figure 23C illustrates the conduit **200** deployed within the collateral channel **112** and the withdrawal of the guide-member **320**, catheter **322**, and access device **324** (e.g., a bronchoscope, endoscope, or similar device). As shown by the arrows of Figure 23C, the conduit **200** maintains the collateral channel **112** so that trapped non-functional air is evacuated from a hyper-inflated lung.

[0223] It is noted that a variation of the inventive method includes using a guide-wire to create the collateral channel and leaving the guide-wire to extend through the collateral channel. Accordingly, a conduit may be advanced over the guide-wire into the collateral channel.

[0224] The invention also contemplates the use of conduits to deliver drugs or medicines to the area of the collateral opening. Also contemplated is the use of a fibrin, cyano-acrylate, or any other bio-compatible adhesive with the conduit to maintain the patency of the collateral channel. For example, the adhesive could be deposited on the exterior of the conduit to maintain patency of the channel. Also, the use of a bioabsorbable material may promote the growth of epithelium on the walls of the conduit. For example, covering the exterior of the conduit with small intestine submucosa, or other bioabsorbable material, may promote epithelium growth thus securing the conduit while the bioabsorbable material eventually absorbs into the body.

[0225] Figure 24 illustrates a variation of a conduit **200** having a one-way valve **330**. The valve **330** allows the conduit **200** to permit exhaust of gas from the air sac but prevents the conduit **200** from serving as another entrance of gas to the air-sac. The valve **330** may be placed at ends of the conduit or within a lumen of the conduit. When such a conduit is deployed in a collateral channel, air may flow into the cage **212**, through the valve **330**, and out the proximal portion **208** of the conduit into an airway thereby releasing excess trapped

air from a lung. The valve **330** may also be used as bacterial in-flow protection for the lungs. A conduit having a valve may be placed in a channel in an airway wall so that air may flow from the parenchymal tissue into the airway and out the lung.

[0226] Figures 25A-25B illustrate another example of deploying a conduit **500** in a channel **510** (or opening) created in a tissue wall **520**. Referring to Figure 25A, a delivery tool **530** carrying a deployable conduit **500** is inserted into the channel **510**. The conduit **500** may include a distal cage structure. The delivery tool **530** is extended straight from an access catheter **540** such that the delivery tool forms an angle  $\beta$  with the tissue wall **520**. It is to be understood that while the tissue wall of airway **522** is shown as being thin and well defined, the present invention may be utilized to maintain the patency of channels and openings which have less well defined boundaries. The delivery tool is further manipulated until the conduit is properly positioned which is determined by, for example, observing the position of a visualization mark **552** on the conduit relative to the opening of the channel **510**.

[0227] Figure 25B illustrates enlarging and securing the conduit in the channel using an expandable member or balloon **560**. The balloon **560** may be radially expanded using fluid (gas or liquid) pressure to deploy the conduit **500**. The balloon may have a cylindrical shape (or another shape such as an hourglass shape) when expanded to 1.) expand the center section and 2.) deflect the proximal and distal sections of the conduit such that the conduit is secured to the tissue wall **520**. During this deployment step, the tissue wall **520** may distort or bend to some degree but when the delivery tool is removed, the elasticity of the tissue tends to return the tissue wall to its initial shape. The delivery tool tends to center the conduit in the channel even when deployed at an angle. Also, it should be noted that despite the inflatable member's cylindrical shape, the conduit is deployed in the proper shape since certain portions of the conduit (e.g., the center section and or cage) are diametrically restricted using control segments. Accordingly, the conduits disclosed herein may be deployed in controlled shapes and inserted into the tissue wall at either a perpendicular (or non-perpendicular ) angle.

[0228] A medical kit for improving gaseous flow within a diseased lung may include a conduit, a hole-making device, a deployment device and/or a detection device. Examples of such methods and devices are described in U.S. Patent Application No. 09/633,651, filed on August 7, 2000; U.S. Patent Application Nos. 09/947,144, 09/946,706, and 09/947,126 all filed on September 4, 2001; and U.S. Patent Application Nos. 10/080,344 and

10/079,605 both filed on February 21, 2002, each of which is incorporated by reference in its entirety. The kit may further contain a power supply, such as an RF generator, or a Doppler controller which generates and analyzes the signals used in the detection devices. The kit may include these components either singly or in combination.

[0229] The kit of the present invention may also contain instructions teaching the use of any device of the present invention, or teaching any of the methods of the present invention. The instructions may actually be physically provided in the kit, or it may be on the covering, e.g., lidstock, of the kit. Furthermore, the kit may also comprise a bronchoscope, or guide-member (such as a guide-wire), or other such device facilitating performance of any of the inventive procedures described herein. All the components of the kit may be provided sterile and in a sterile container such as a pouch or tray. Sterile barriers are desirable to minimize the chances of contamination prior to use.

[0230] Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

[0231] All of the features disclosed in the specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

## CLAIMS

1. A conduit comprising:  
a center section comprising a first end, a second end and a center-section passageway extending from said first end to said second end;  
a plurality of first extension members extending from said first end, said first extension members being deflectable about said first end of said center section; and  
a cage structure adjacent to said second end, said cage structure having at least one opening and at least one cage passageway in fluid communication with said center-section passageway.
2. The conduit of claim 1 wherein said conduit comprises a wire frame.
3. The conduit of claim 1 wherein said cage structure is connected to said second end of said center section by a plurality of second extension members, said second extension members being outwardly deflectable about said second end of said center section.
4. The conduit of claim 1 wherein said cage structure is connected directly to said second end of said center section.
5. The conduit of claim 1 further comprising a tissue barrier coaxially surrounding at least a portion of said center section.
6. The conduit of claim 5 wherein said tissue barrier at least partially surrounds said center section and at least partially surrounds said cage structure.
7. The conduit of claim 6 further comprising a visualization mark, said visualization mark being visually distinct from another portion of said conduit.
8. The conduit of claim 7 wherein said visualization mark is an opaque ring.
9. The conduit of claim 7 wherein said visualization mark is a white ring.
10. The conduit of claim 9 wherein said visualization mark comprises titanium dioxide.

11. The conduit of claim 5 further comprising a bioactive substance on said tissue barrier.
12. The conduit of claim 1 wherein said conduit is radially expandable.
13. The conduit of claim 12 wherein said cage structure has an unexpanded diameter and an expanded diameter at a point along the cage passageway and wherein a ratio of said unexpanded diameter to said expanded diameter ranges from 1:2 to 1:4.
14. The conduit of claim 1 wherein said cage structure comprises a plurality of elongate cage members.
15. The conduit of claim 14 wherein at least one of said cage members has an axially extendable length.
16. The conduit of claim 15 wherein said at least one extendable cage member has a zigzag region which may be straightened.
17. The conduit of claim 2 wherein said wire frame structure is plastically deformable.
18. The conduit of claim 2 wherein said first extension members outwardly deflect when the first extension members are not restrained.
19. The conduit of claim 1 wherein each of said first extension members comprises a fixed end and a movable tapered end, said movable tapered end having a width less than the width of said first extension member at said fixed end.
20. The conduit of claim 14 wherein each of said elongate cage members comprises a tapered end.
21. The conduit of claim 14 wherein said cage members form a tubular shape.
22. The conduit of claim 3 wherein said cage members form a tubular shape.
23. The conduit of claim 4 wherein said cage structure is comprised of a plurality of elongate cage members and wherein each of said cage members has a fixed end attached to said second end of said center section, an intermediate section, and a free end distal to said intermediate section wherein a portion of each said cage member between said intermediate

section and said fixed end may outwardly deflect such that said portion is substantially transverse to said center section passage.

24. The conduit of claim 14 further comprising cage-control segments that link adjacent cage members and limit radial expansion of said cage structure.

25. The conduit of claim 1 wherein each of said first extension members comprises a fixed end and a free end, said fixed end attached to said first end of said center section at a weakened region of reduced cross sectional area.

26. The conduit of claim 25 wherein said weakened region has a reduced thickness.

27. The conduit of claim 12 wherein said conduit is adapted to axially shrink while radially expanding.

28. The conduit of claim 5 wherein said tissue barrier comprises a material selected from the group consisting of silicone and urethane.

29. The conduit of claim 2 wherein said wire frame comprises a material selected from the group consisting of stainless steel, titanium, titanium alloy, nitinol, and MP35N.

30. The conduit of claim 1 wherein said cage structure has an axial length ranging from 2 to 20 mm.

31. The conduit of claim 12 further comprising at least one center-control segment configured to restrict radial expansion of said center-section passageway to a maximum diameter.

32. The conduit of claim 5 wherein said tissue barrier coaxially surrounds said proximal extension members and wherein said conduit further comprises at least one membrane-tearing support extending from one of said first extension members to an adjacent first extension member such that when said first extension members are outwardly deflected, said at least one membrane-tearing support straightens and holds the tissue barrier at a point between adjacent outwardly deflected first extension members.

33. The conduit of claim 6 wherein said cage structure comprises a plurality of elongate cage members and said tissue barrier coaxially surrounds said cage structure and wherein

said conduit further comprises at least one membrane-tearing support extending from one of said cage members to an adjacent cage member such that when said cage members are outwardly deflected, said at least one membrane-tearing support straightens and holds the tissue barrier at a point between adjacent deployed cage members.

34. The conduit of claim 1 wherein said at least one opening is at said end of said cage structure.

35. The conduit of claim 1 wherein said at least one opening is in a side wall of said cage structure.

36. The conduit of claim 2 further comprising a bioactive substance on said wire frame.

37. A conduit having an undeployed state for facilitating delivery to a channel in a lung and a deployed state, different than the undeployed state, for maintaining the patency of the channel, said conduit comprising:

a radially expandable frame having a proximal section, a center section and a distal section, said proximal section comprising a plurality of proximal extension members, said center section comprising a first end at which said plurality of proximal extension members are attached, a second end, and a center-section passage extending from said first end to said second end, said distal section comprising a cage distal to said center section and said cage comprising at least one opening and at least one cage passage which is in fluid communication with said center-section passage wherein when said conduit is in said undeployed state, said proximal section, said center section and said distal section have a reduced profile, and when said conduit is in said deployed state, said plurality of extension members deflect outward forming a non-zero angle with an axis of said center-section passage, and said cage has an expanded profile greater than that of said cage when said conduit is in said undeployed state.

38. The conduit of claim 37 wherein each of said proximal extension members comprises at least one aperture.

39. The conduit of claim 37 wherein said cage is connected to said second end of said center section by a plurality of second extension members, said second extension members being deflectable about said second end of said center section.



40. The conduit of claim 37 wherein said cage comprises a plurality of cage members that are directly connected with said second end of said center section, each of said cage members having a fixed end, a movable end, and an intermediate segment therebetween, said fixed end being attached to said center section second end, and wherein said intermediate segment and said movable end are adapted to assume a cage shape when not constrained.
41. The conduit of claim 37 wherein said cage in said expanded profile has a varying diameter.
42. The conduit of claim 37 wherein said conduit in said undeployed state has a constant diameter.
43. The conduit of claim 41 wherein said cage has a first end and a second end and said diameter is greater in a middle portion between said first end and said second end.
44. The conduit of claim 37 wherein each of said proximal extension members comprises a weakened portion of reduced cross section such that each of said proximal extension members bends at said weakened portion when a radially outward force is applied to said proximal extension members.
45. The conduit of claim 37 wherein said center section is radially expandable and said center section has a greater diameter in said deployed state than in said undeployed state.
46. The conduit of claim 45 further comprising at least one center-control segment configured to restrict radial expansion of said center-section passageway to a maximum diameter.
47. The conduit of claim 46 wherein said at least one center-control member has an arcuate shape when said center section is not radially expanded.
48. The conduit of claim 47 wherein said center section has a plurality of ribs and said center control segment joins two adjacent ribs.
49. The conduit of claim 37 wherein said cage has an axial length ranging from 2 to 20 mm when deployed.

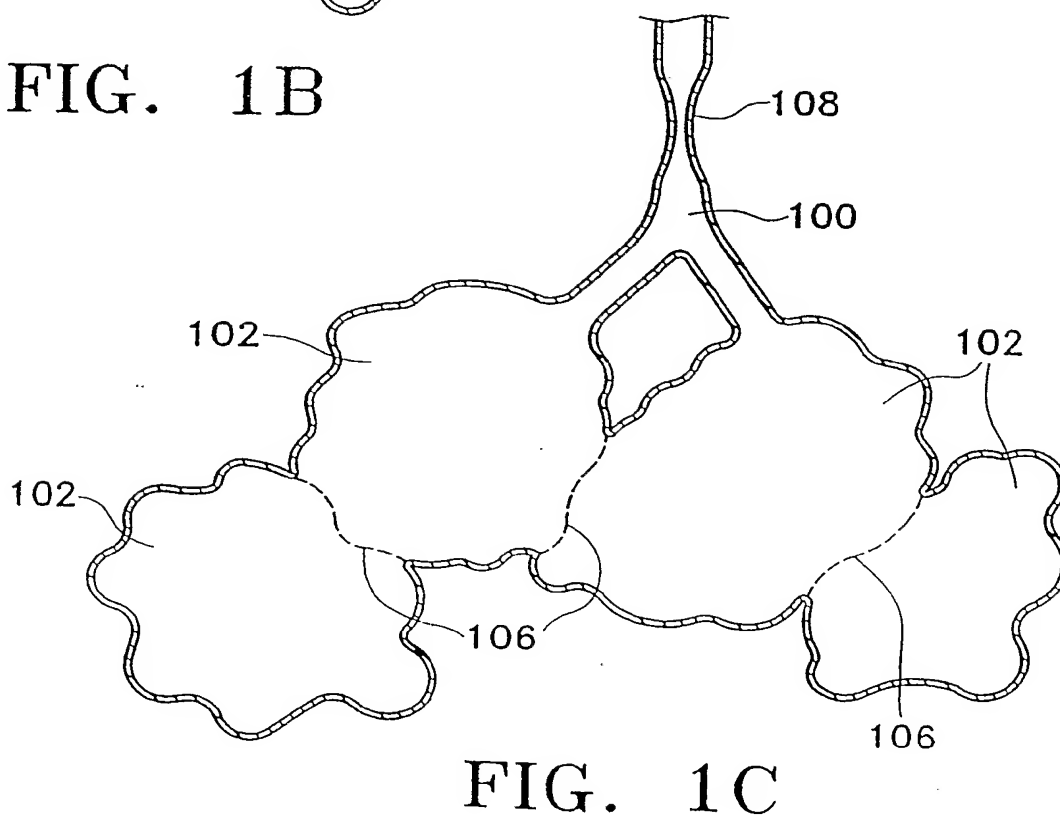
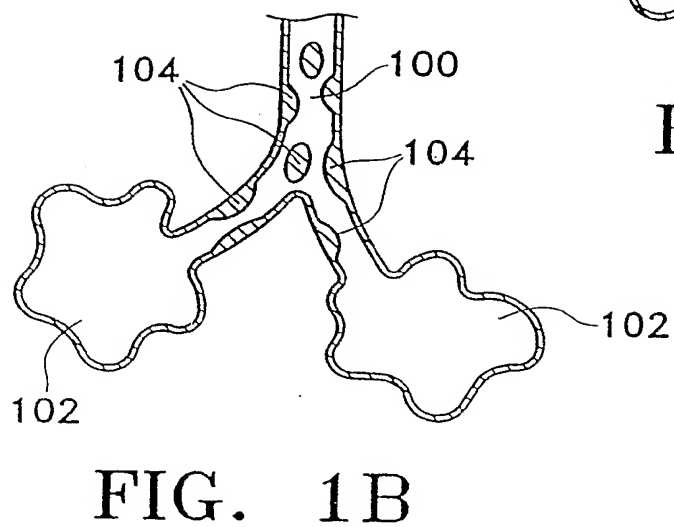
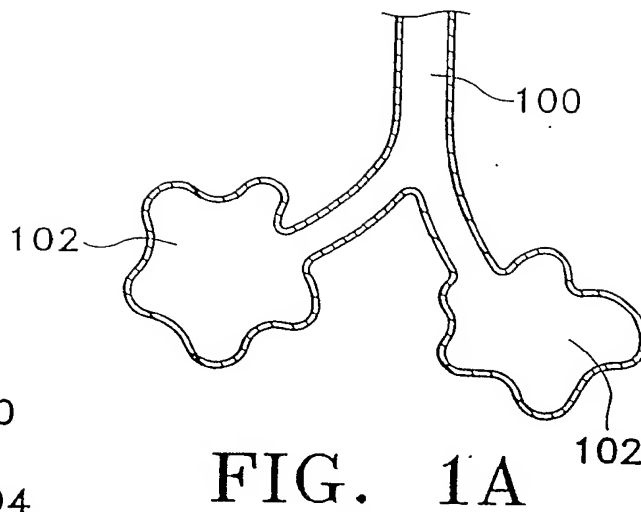
50. The conduit of claim 37 further comprising a biocompatible coating coaxially surrounding at least a portion of said frame.
51. The conduit of claim 39 wherein said proximal extension members and said distal extension members, when said conduit is in said deployed state, are deflected from said axis of said center-section passage such that tissue may be compressed between opposing proximal and distal extension members when said conduit is deployed in a channel.
52. The conduit of claim 51 wherein said proximal and distal extension members are configured such that, when said conduit is in said deployed state, said opposing proximal and distal extension members deflect to a degree such that a V-shape is formed when viewed from a side view.
53. The conduit of claim 37 wherein said cage passage, when deployed, has a greater diameter than that of said center-section passage, when deployed.
54. The conduit of claim 37 wherein said cage passage, when deployed, has a varying diameter from a first end of said cage passage to a second end of said cage passage, when deployed.
55. The conduit of claim 50 further comprising a bioactive substance disposed on at least a portion an outer surface of said conduit.
56. A conduit for maintaining the patency of a channel created in lung tissue, said conduit comprising:
- a center section having a proximal end and a distal end and a center section passage within said center section extending between said ends;
  - a plurality of extension members comprising at least one proximal extension member and at least one distal extension member, said at least one proximal extension member having a fixed end attached to said proximal end of said center section and said at least one distal extension member having a fixed end attached to said distal end of said center section, each of said proximal and distal extension members having a free end being moveable such that said extension members may rotate about each of said ends of said center section to retain said tissue between said extension members; and

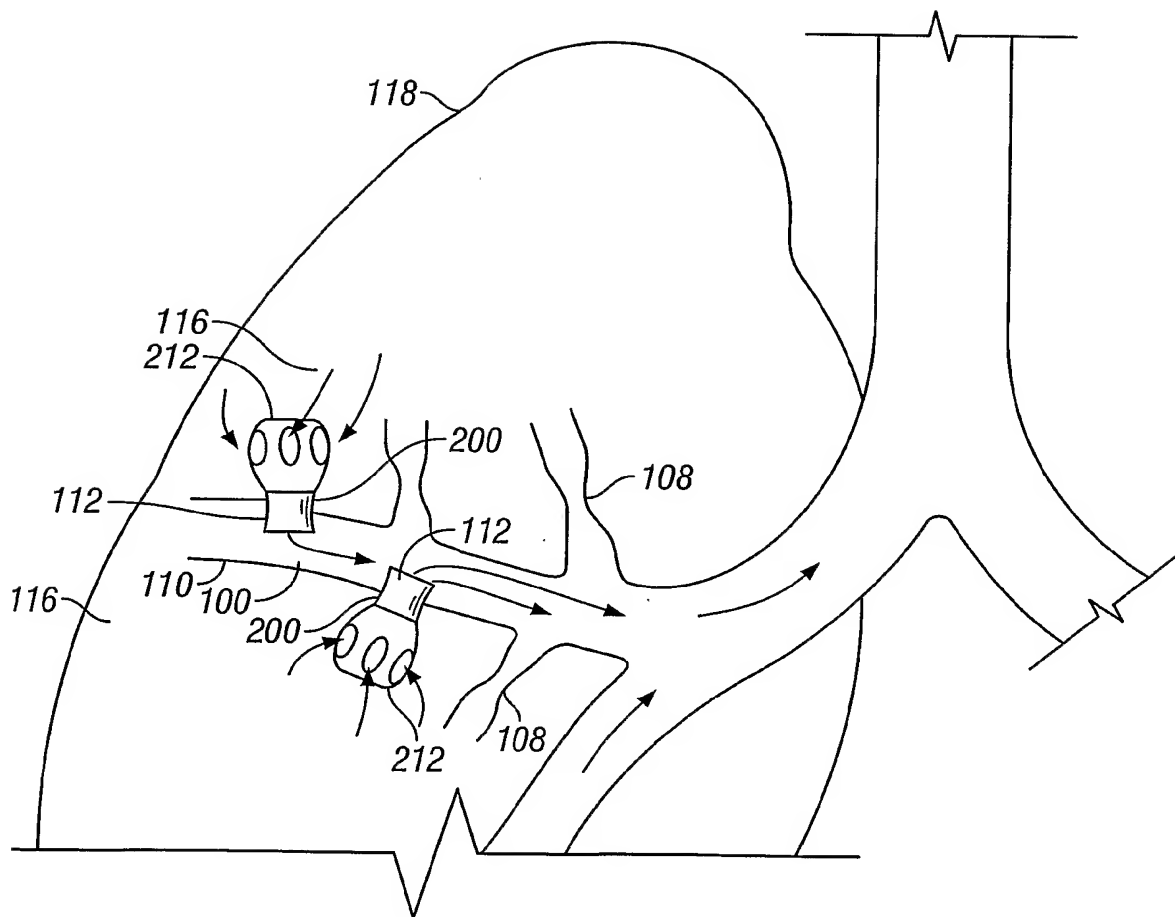
a cage adjacent to said distal end of said center section, said cage having at least one opening and a cage passage in fluid communication with said center section passage.

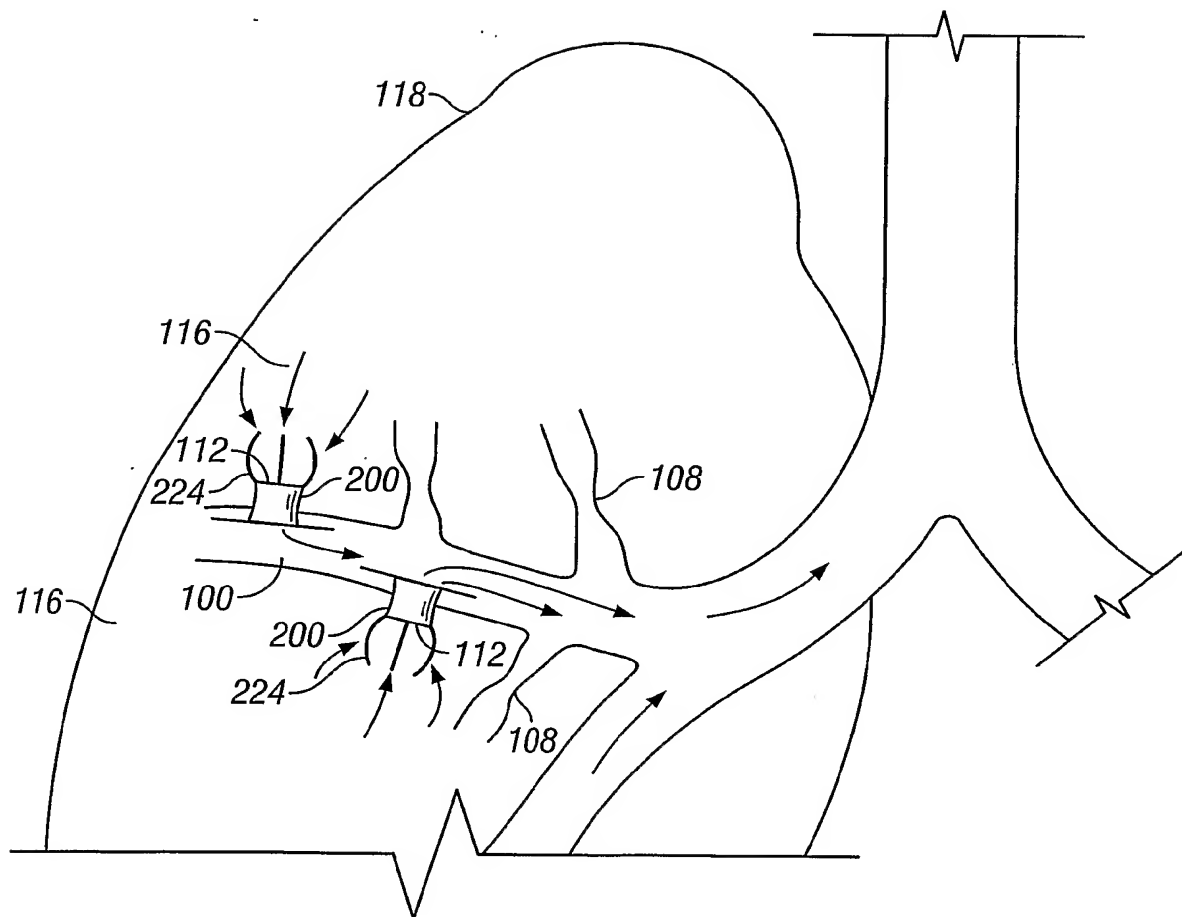
57. The conduit of claim 56 wherein said cage comprises a plurality of elongate members.
58. The conduit of claim 56 wherein said cage comprises a tubular body comprising a plurality of apertures in said body of said cage, each of said apertures in fluid communication with said cage passage.
59. A method for maintaining the patency of a channel in lung tissue comprising:  
deploying a medical device in said channel said medical device having a passageway extending from one open end to a second open end.
60. The method of claim 59 wherein said medical device is a conduit as recited in claim 1.
61. The method of claim 60 wherein deploying is performed with a balloon catheter having an inflatable member.
62. The method of claim 60 further comprising delivering a bioactive substance to the tissue.
63. The method of claim 62 wherein the bioactive substance is a coating on the conduit.
64. The method of claim 62 wherein the substance is delivered by a delivery catheter prior to deploying the conduit.
65. The method of claim 61 wherein said balloon catheter comprises an opaque band coaxially surrounding a region of said inflatable member.
66. The method of claim 59 wherein said channel is a hole through an airway wall.
67. A kit comprising:  
a conduit as recited in claim 1; and  
a deployment catheter to deploy the conduit.
68. The kit as recited in claim 67 further comprising a guidewire.

69. The kit as recited in claim 67 wherein said deployment catheter is a balloon catheter.

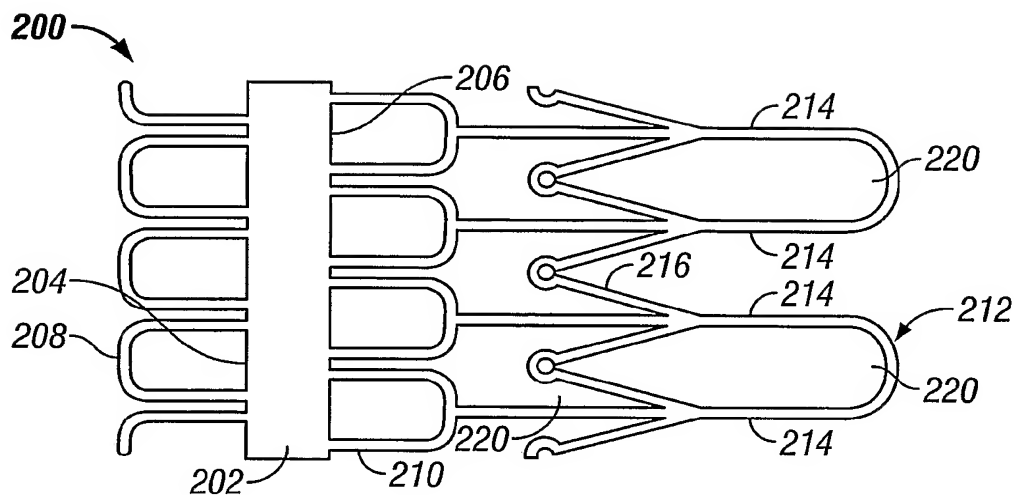
70. The kit as recited in claim 67 further comprising an instrument for creating holes in an airway wall.



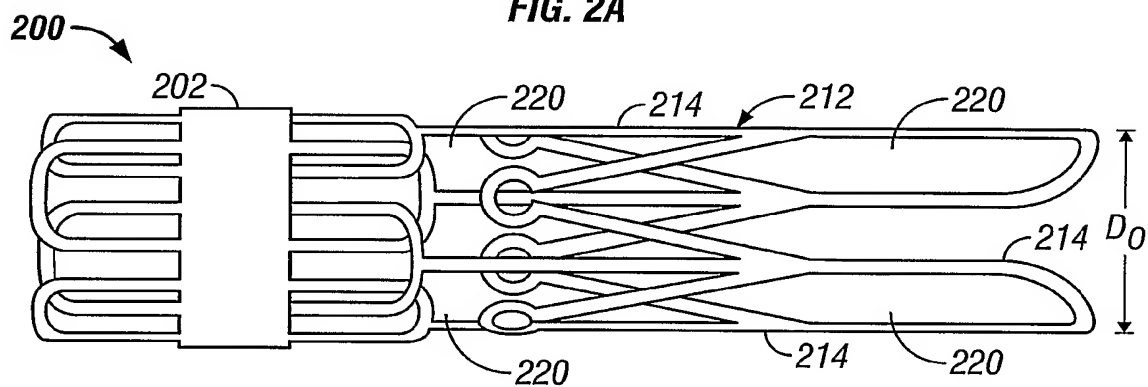
**FIG. 1D**



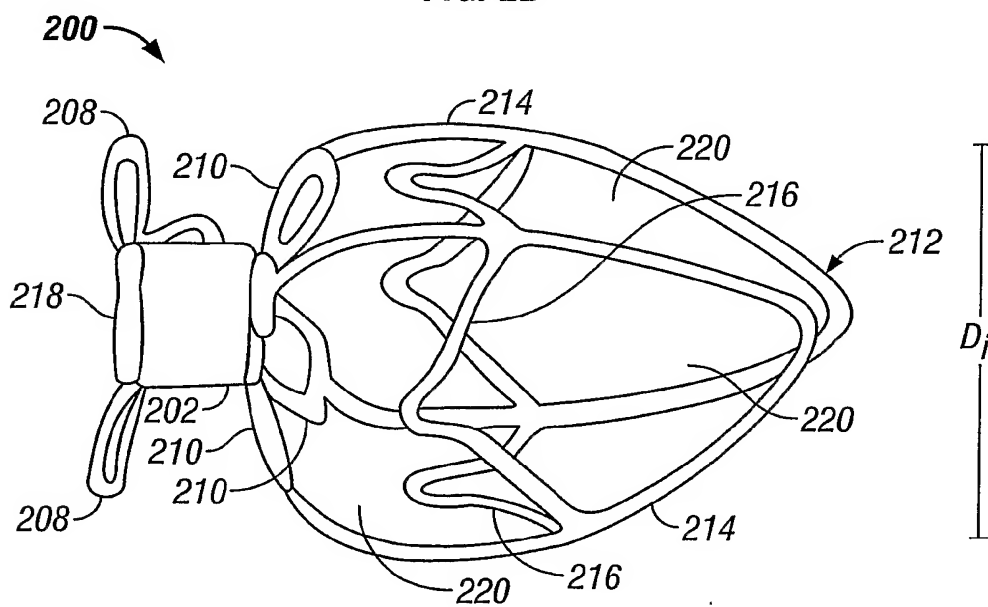
**FIG. 1E**



**FIG. 2A**

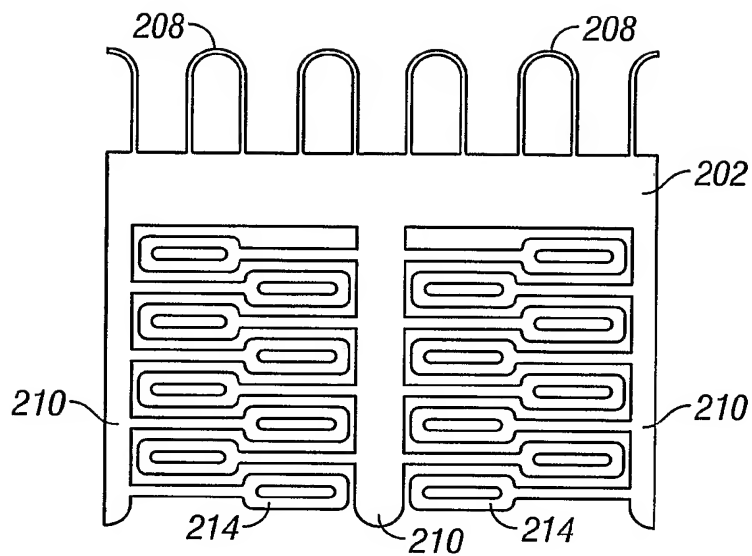


**FIG. 2B**

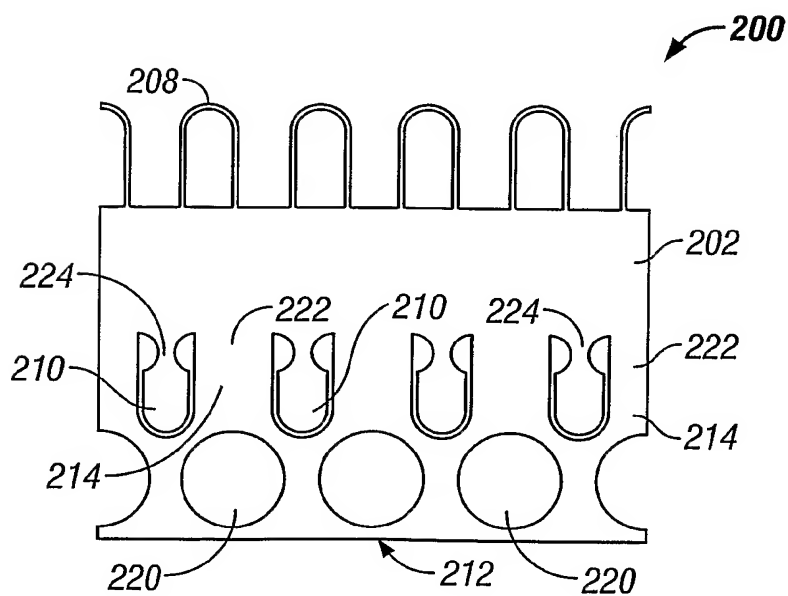


**FIG. 2C**





**FIG. 3**



**FIG. 4**

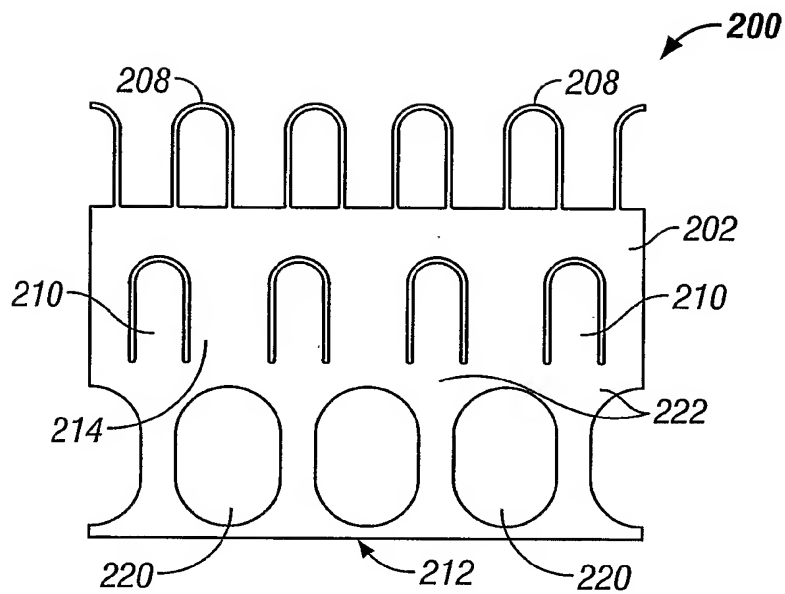


FIG. 5

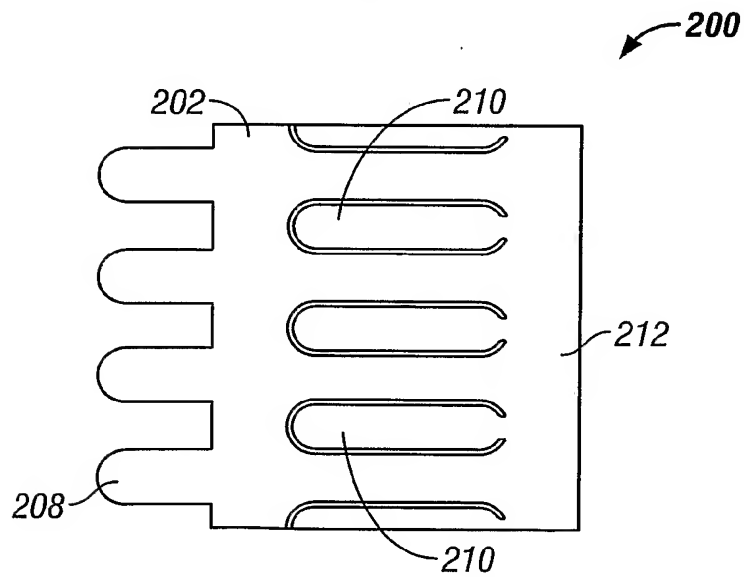


FIG. 6

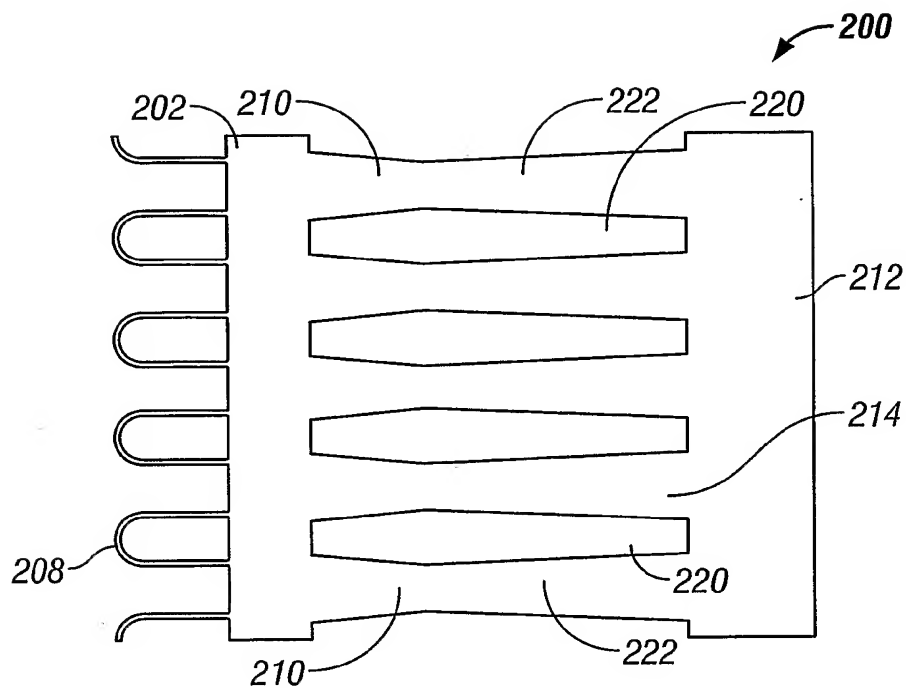


FIG. 7A

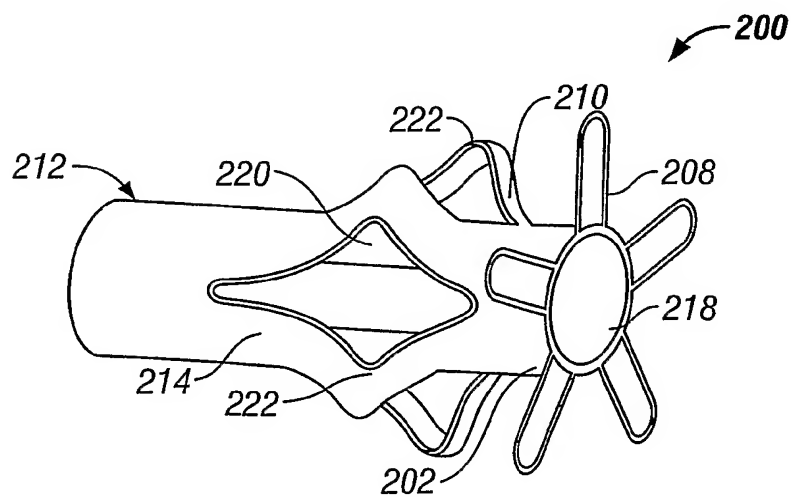
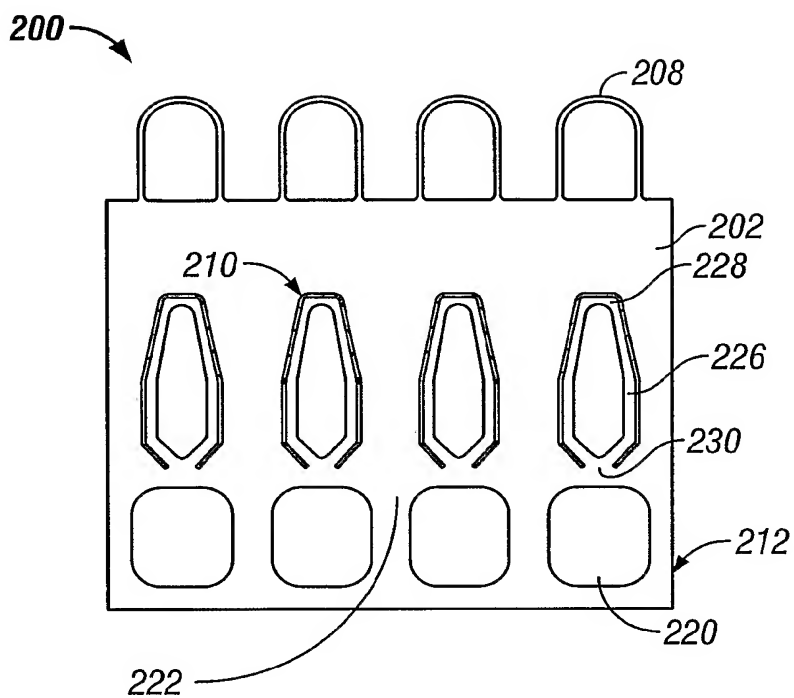
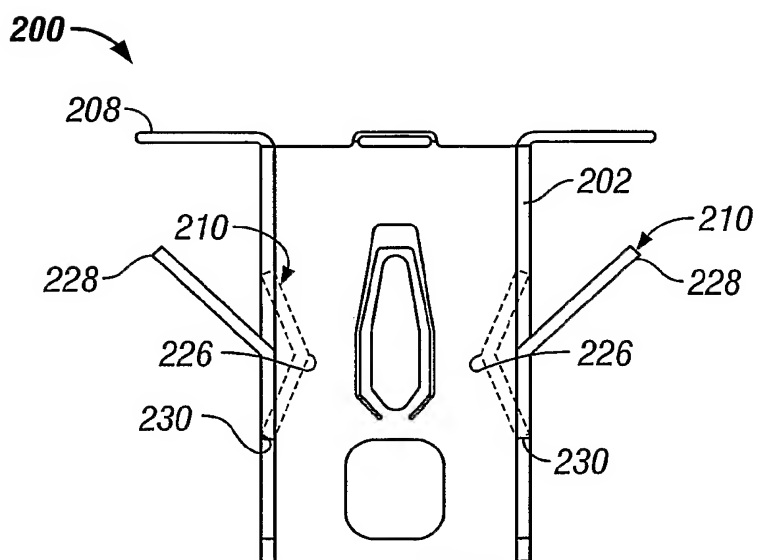
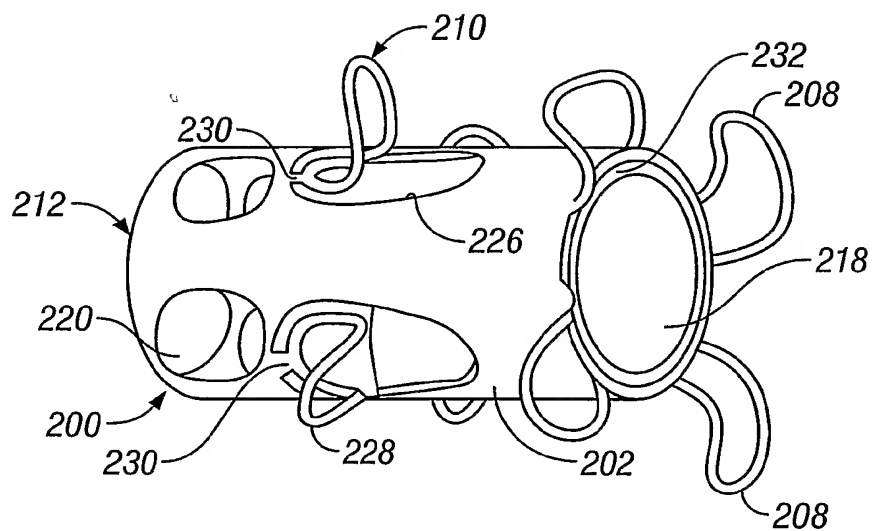
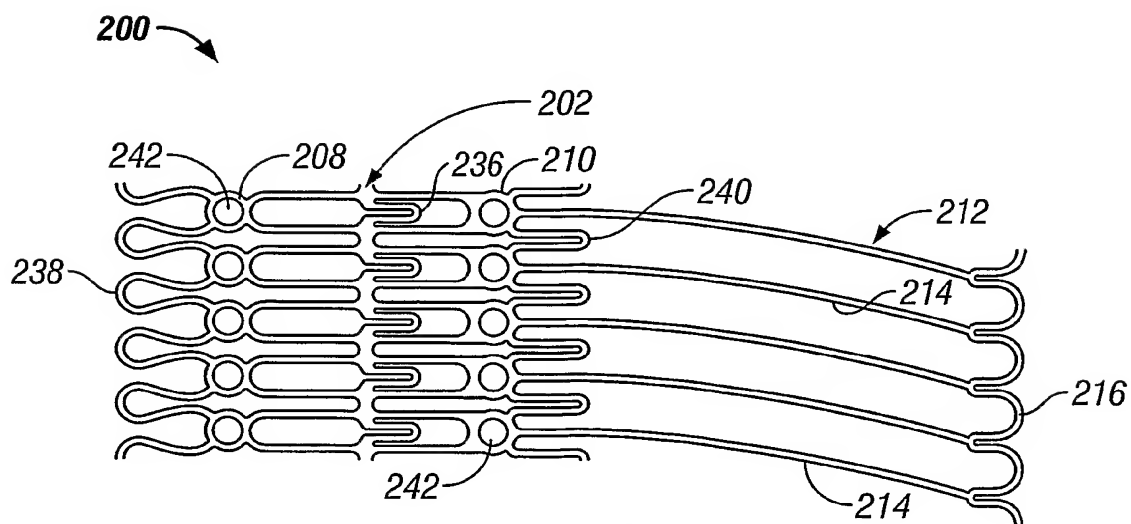


FIG. 7B

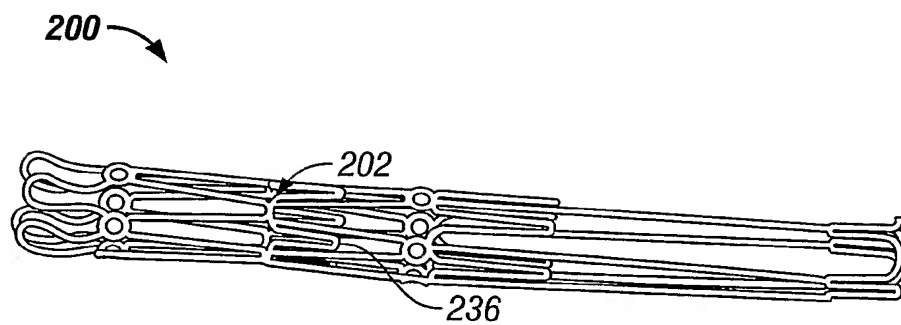
**FIG. 8A****FIG. 8B**



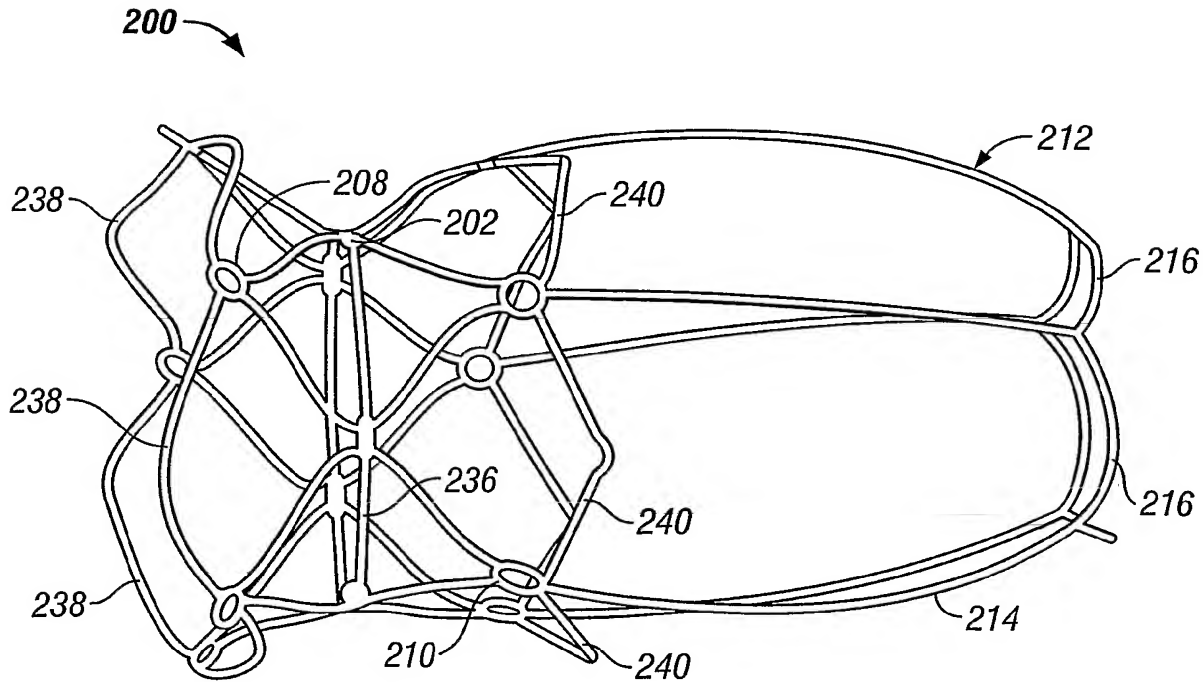
**FIG. 8C**



**FIG. 9A**



**FIG. 9B**



**FIG. 9C**

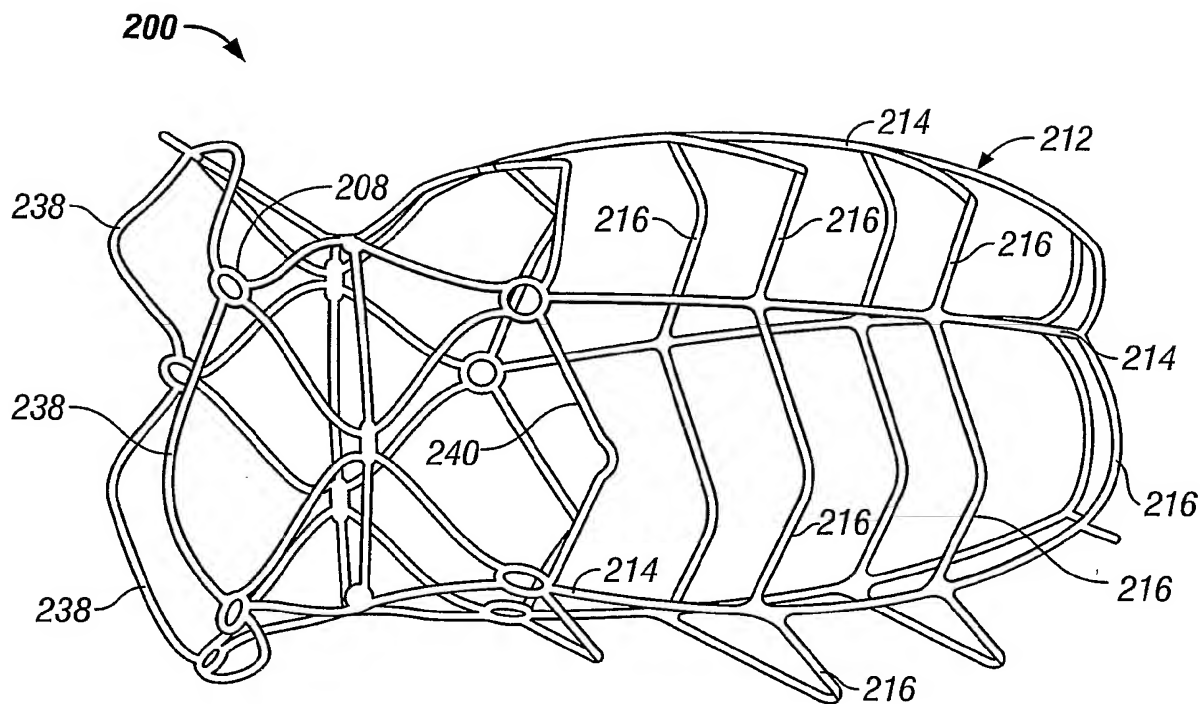


FIG. 9D

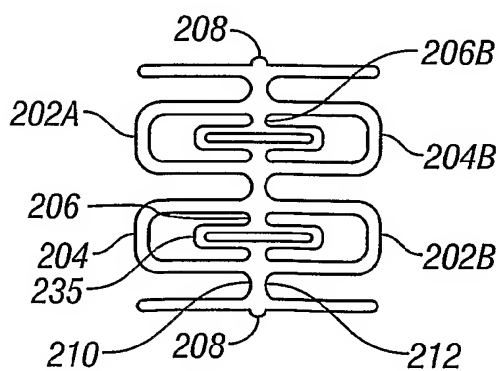


FIG. 9E

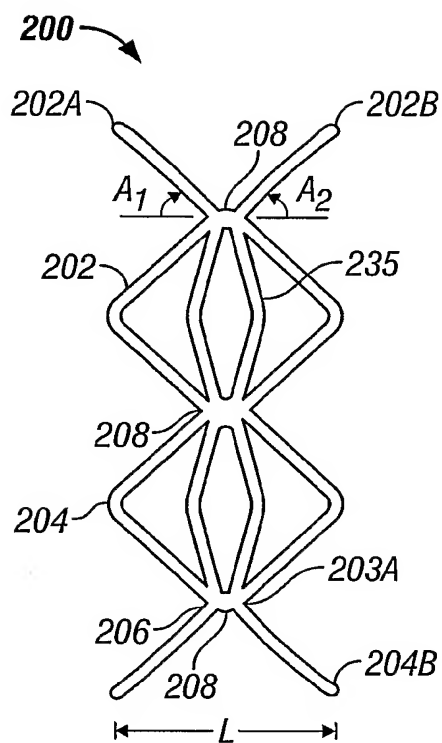


FIG. 9F

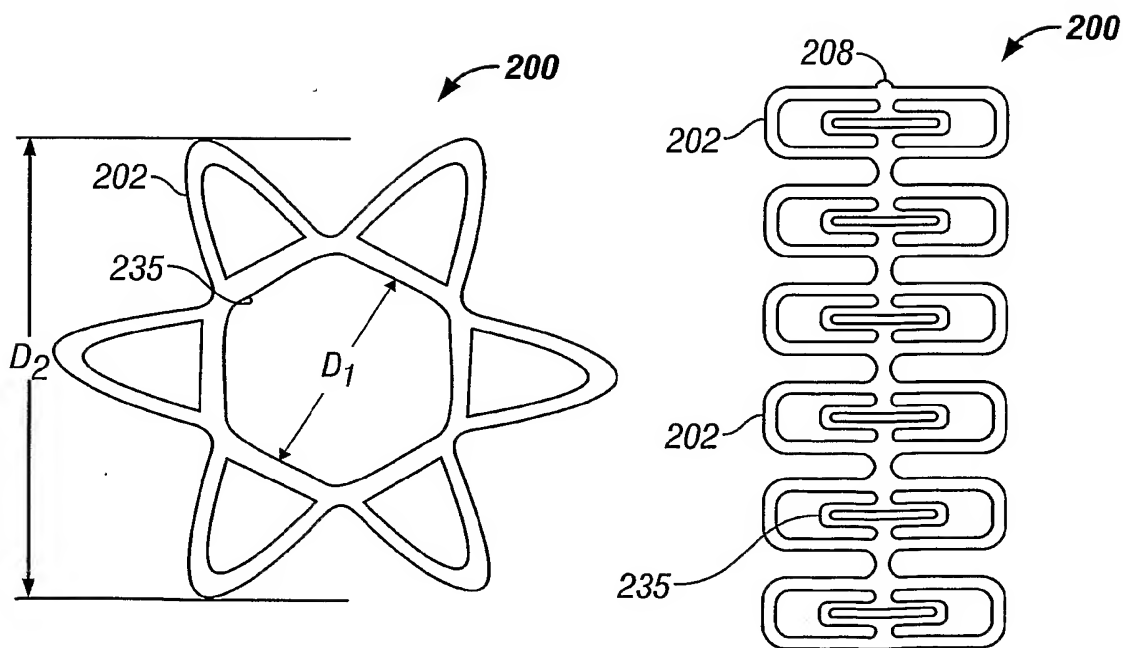


FIG. 9G

FIG. 9H



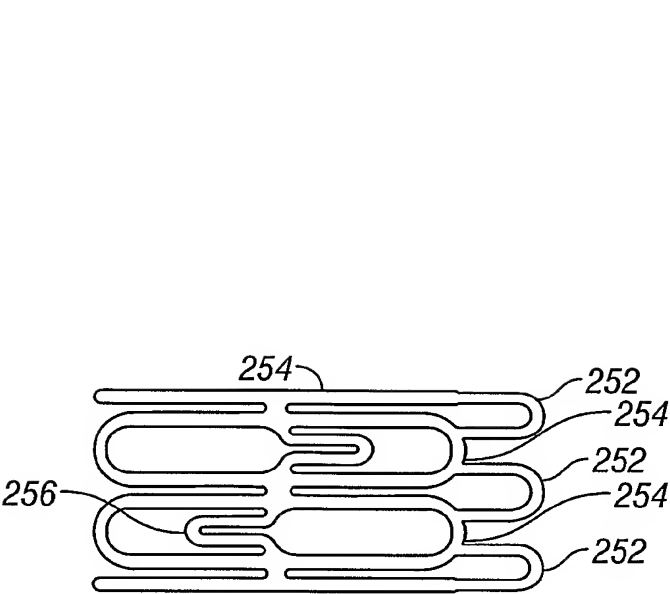


FIG. 9I

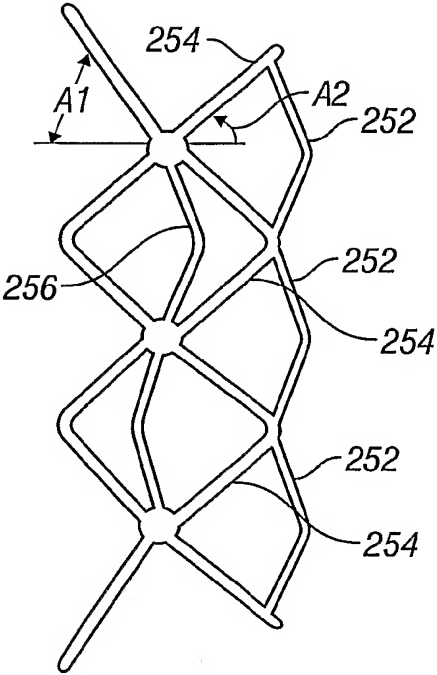


FIG. 9J

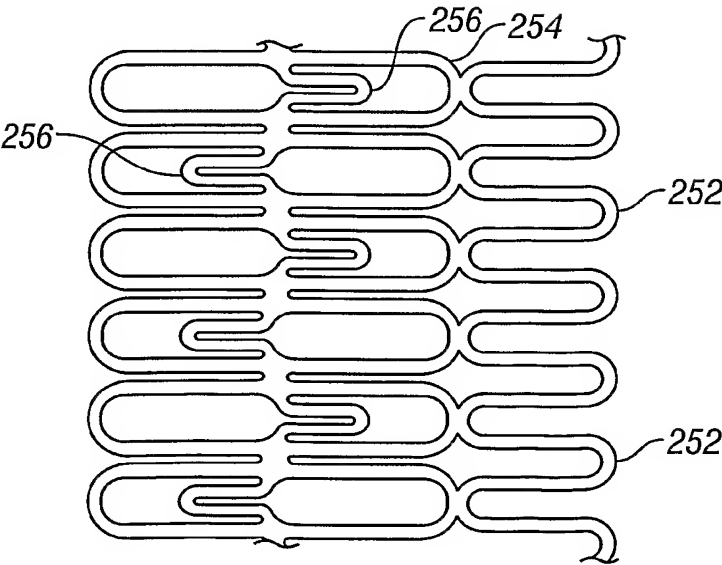


FIG. 9K

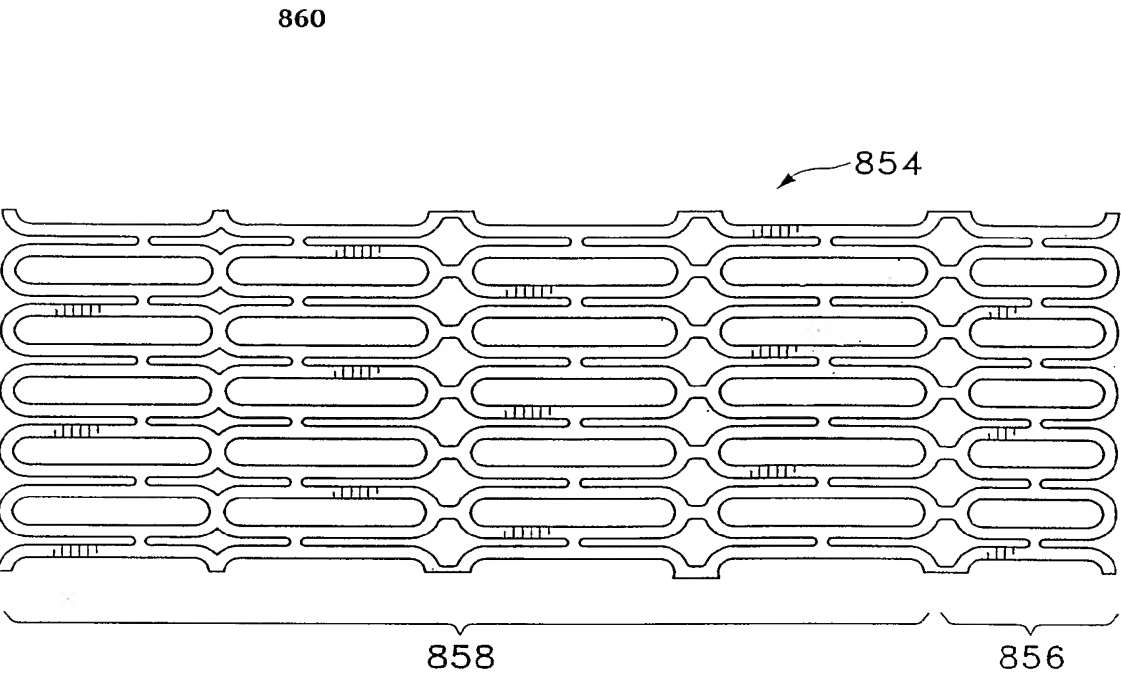


FIG. 9L

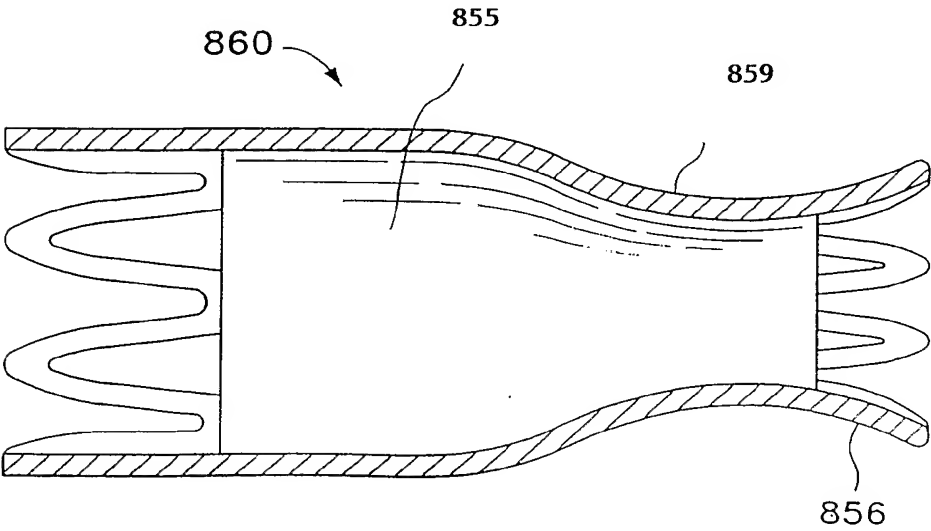


FIG. 9M

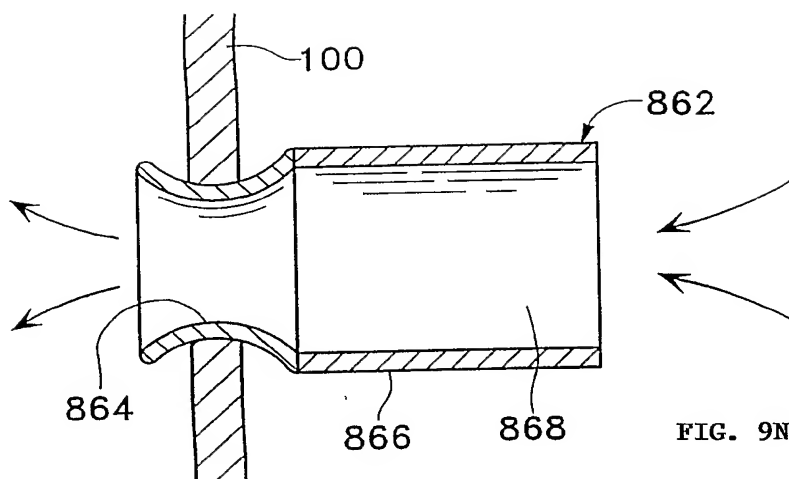


FIG. 9N

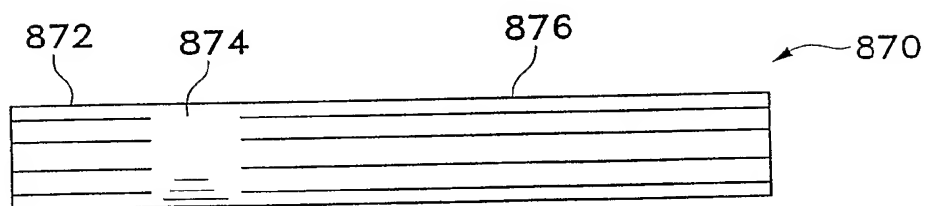


FIG. 90

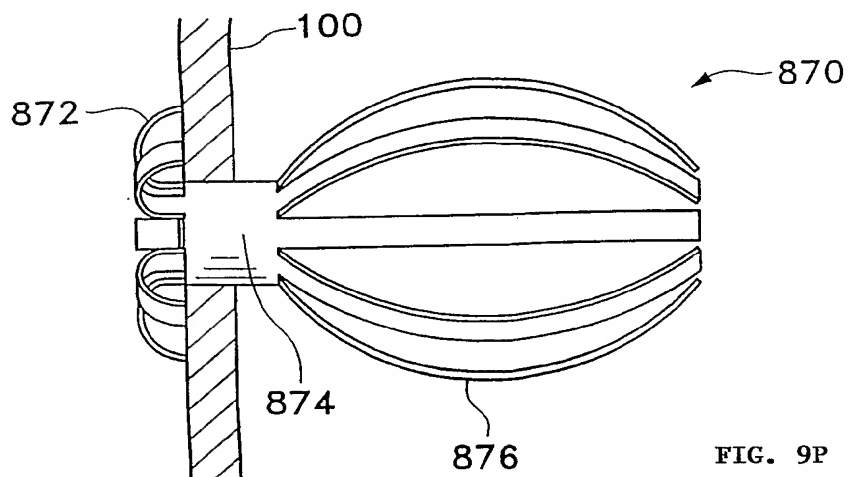
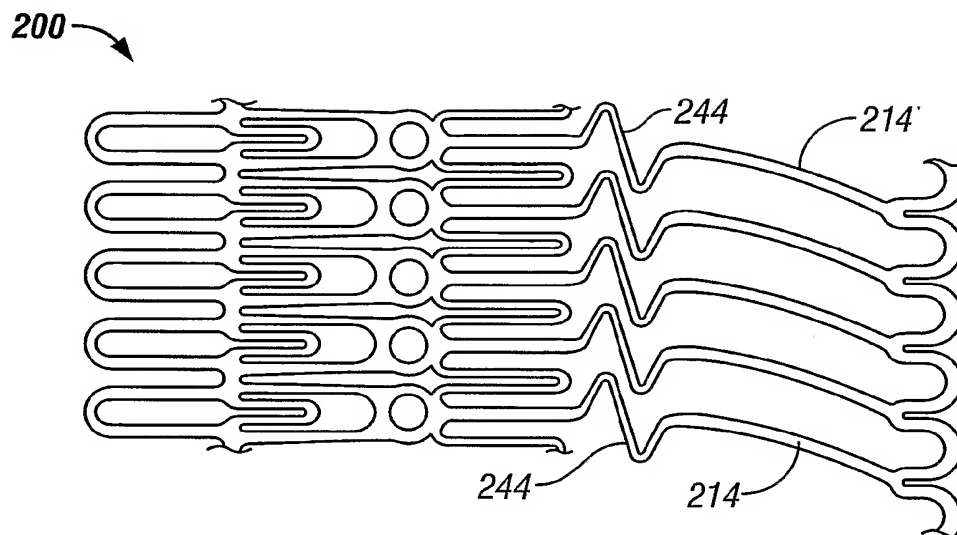
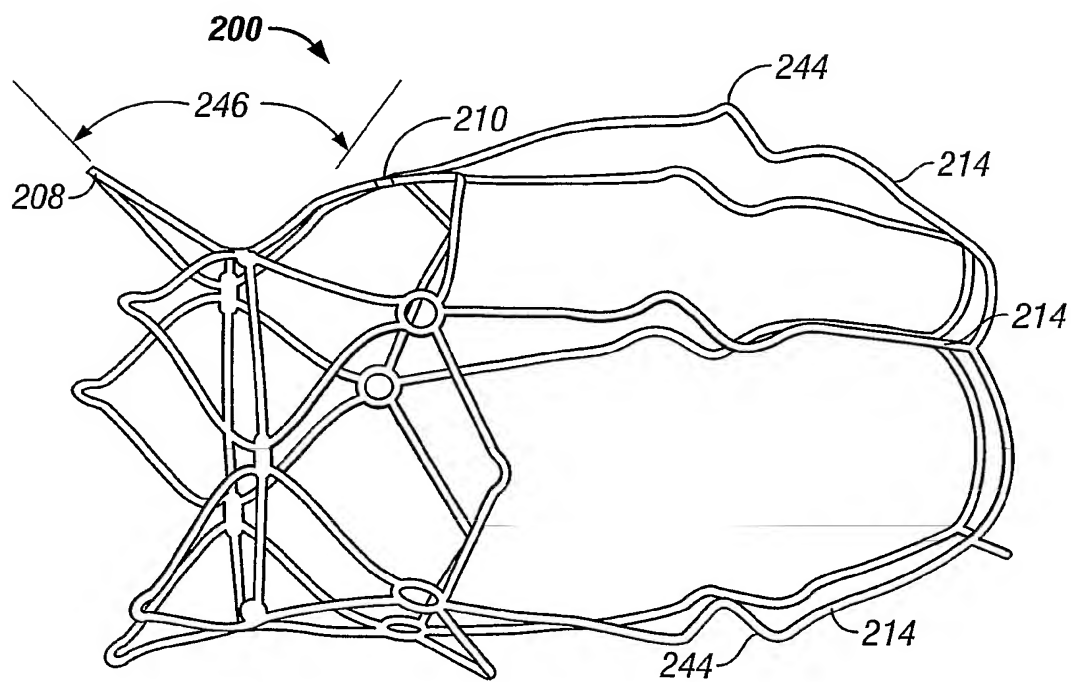
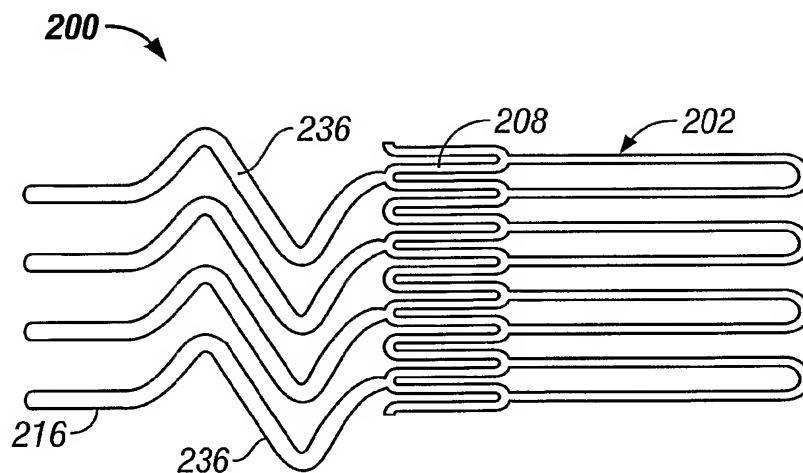
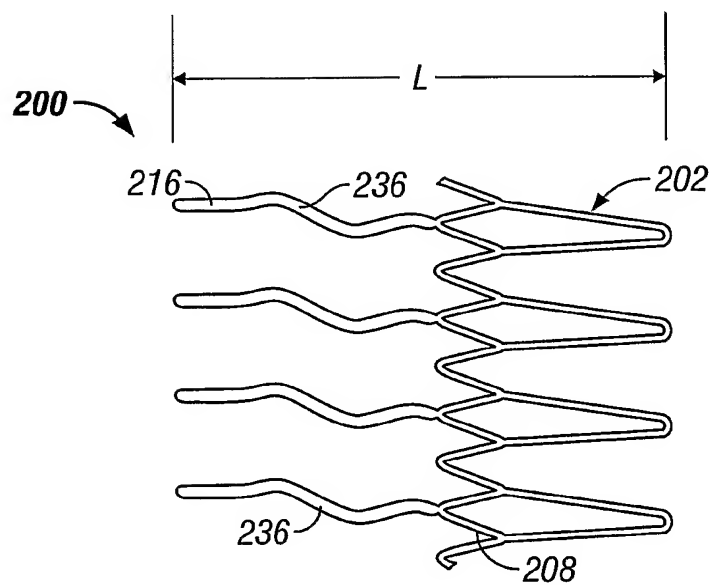


FIG. 9P

**FIG. 10A****FIG. 10B**

**FIG. 10C****FIG. 10D**

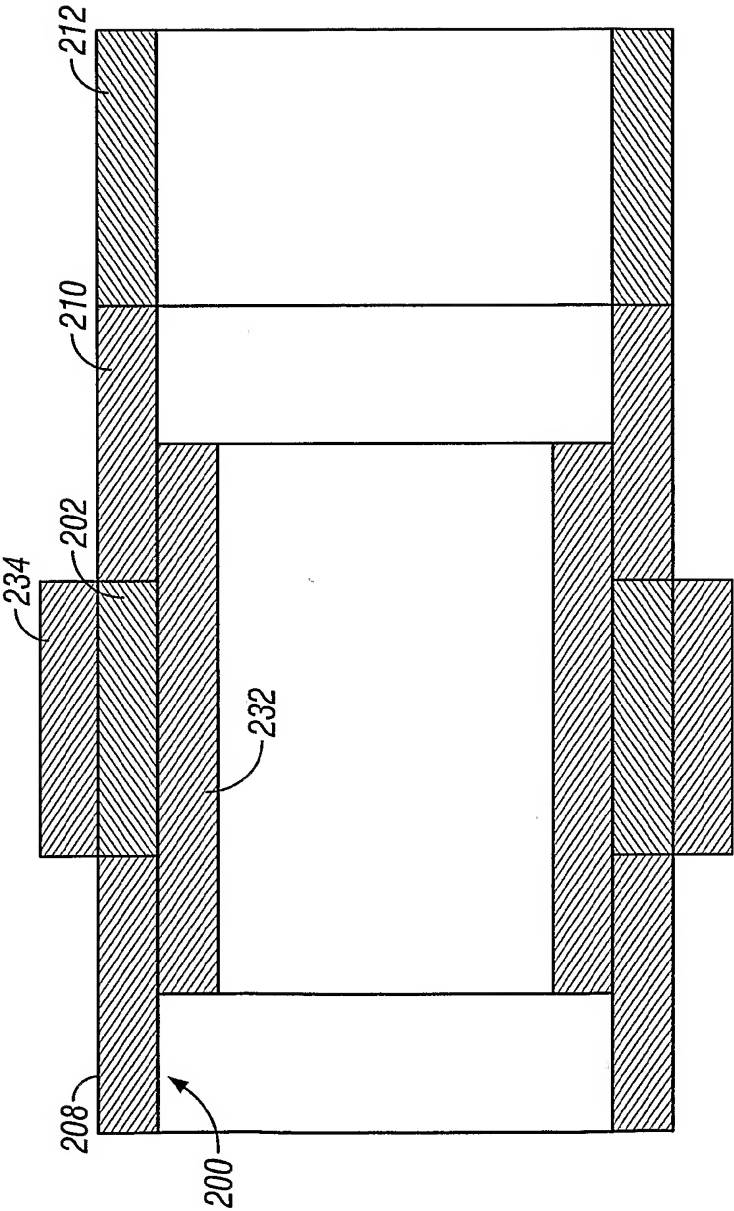


FIG. 11

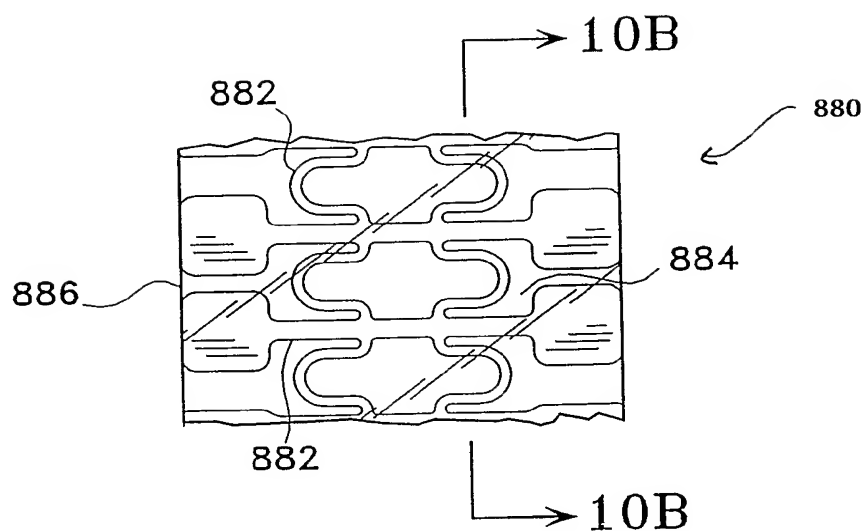


FIG. 12A

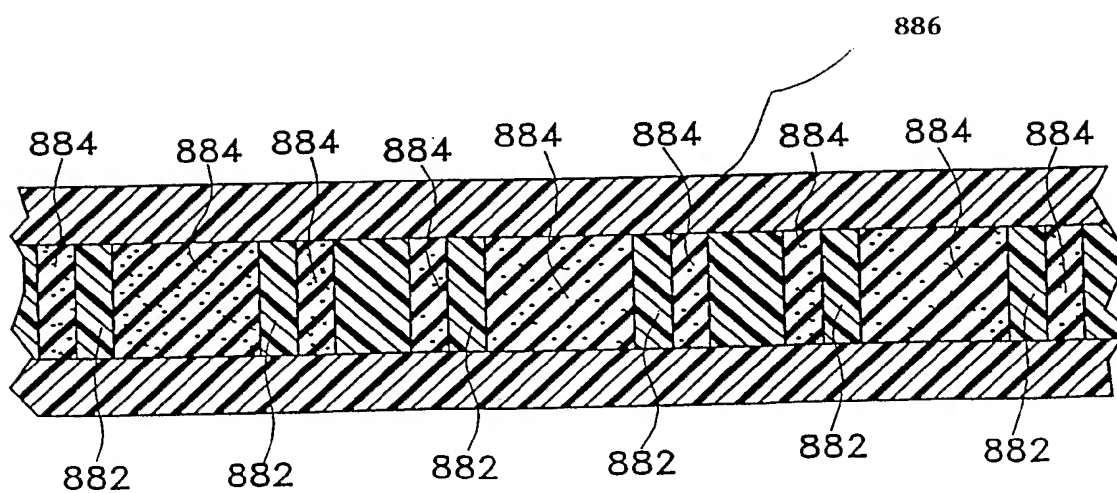


FIG. 12B

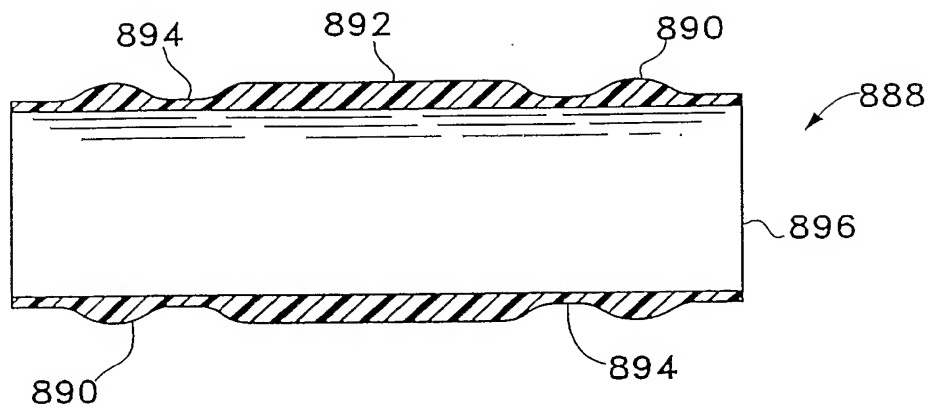


FIG. 13A

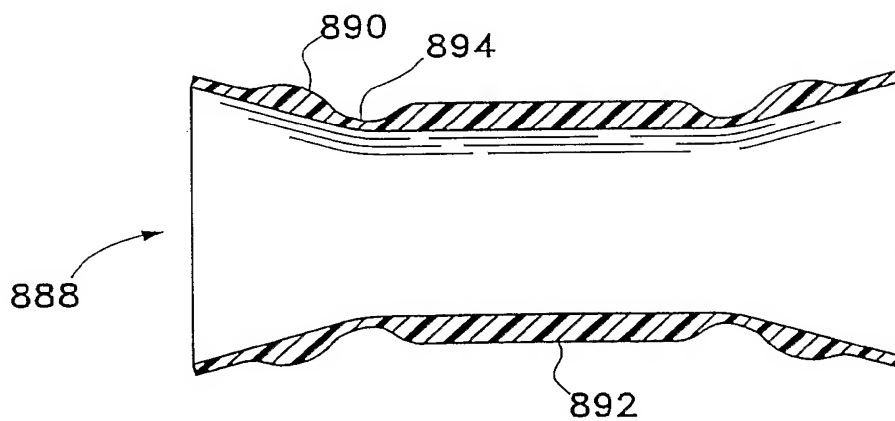


FIG. 13B

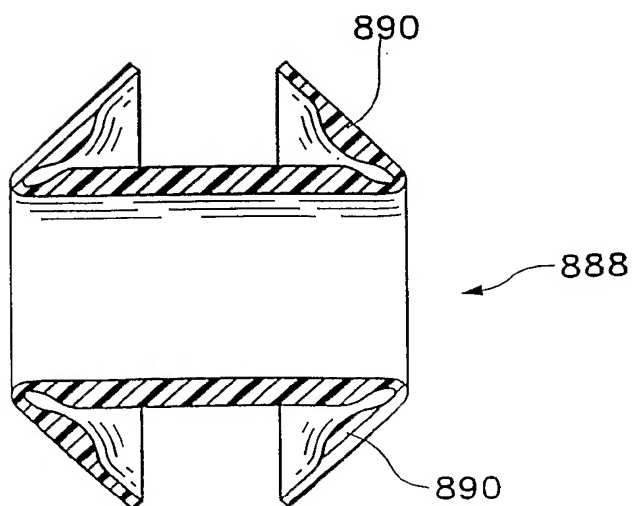


FIG. 13C



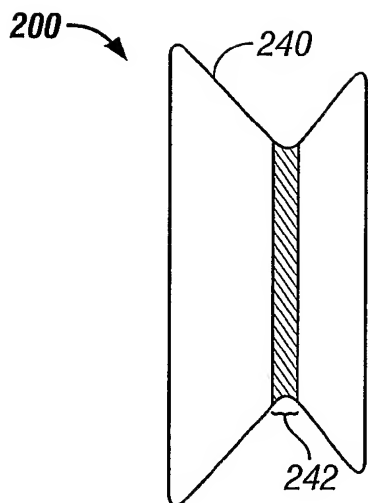


FIG. 14A

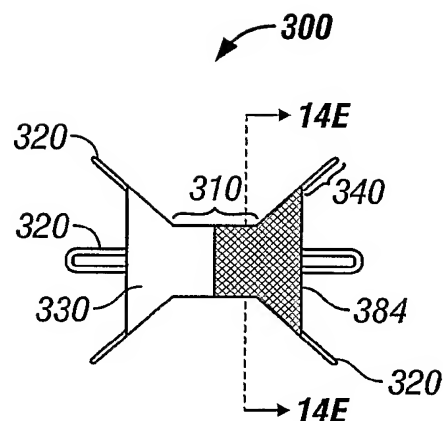


FIG. 14B

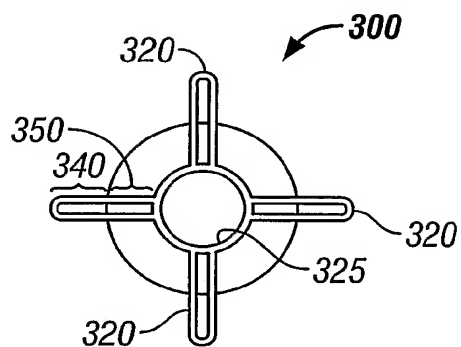


FIG. 14C

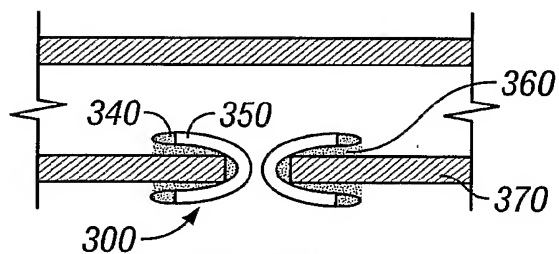


FIG. 14D

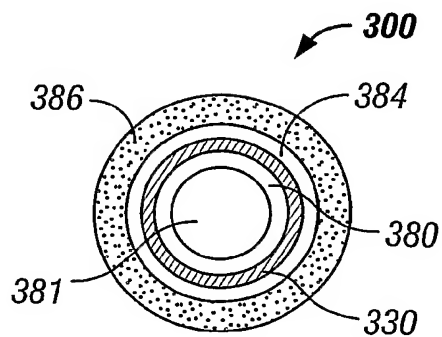
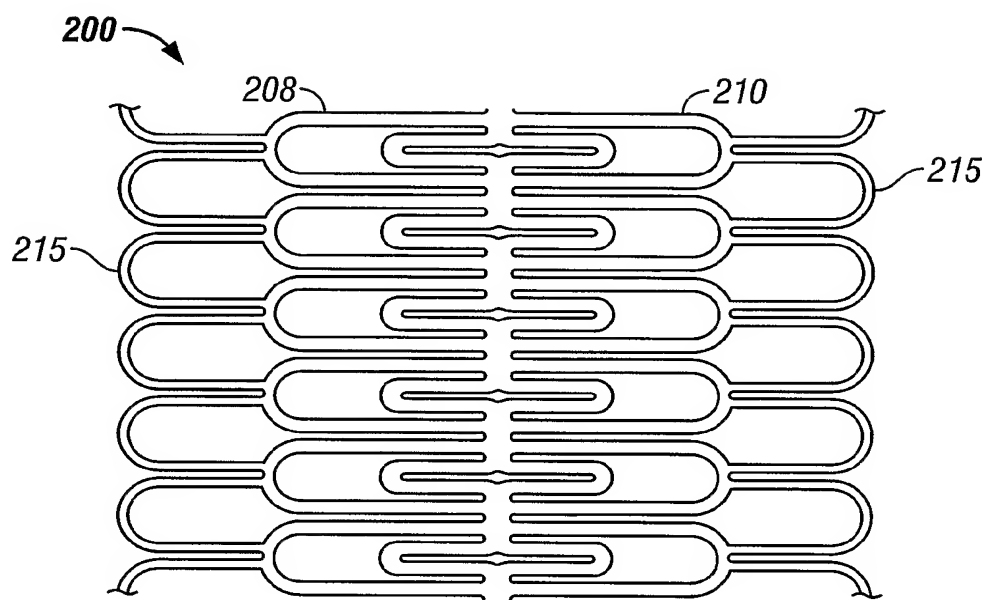
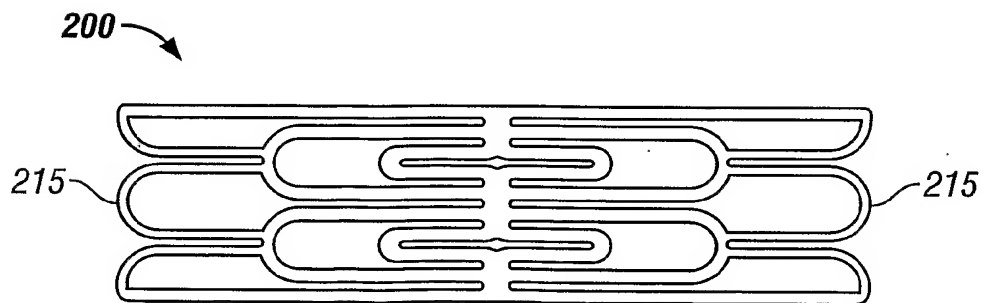
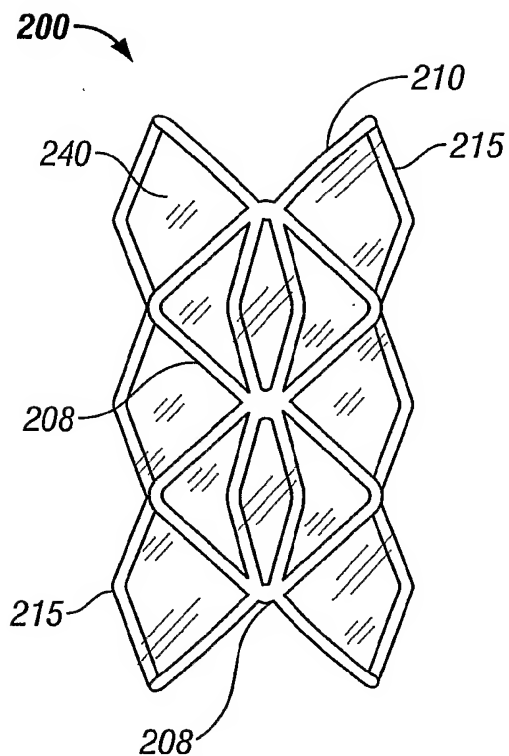
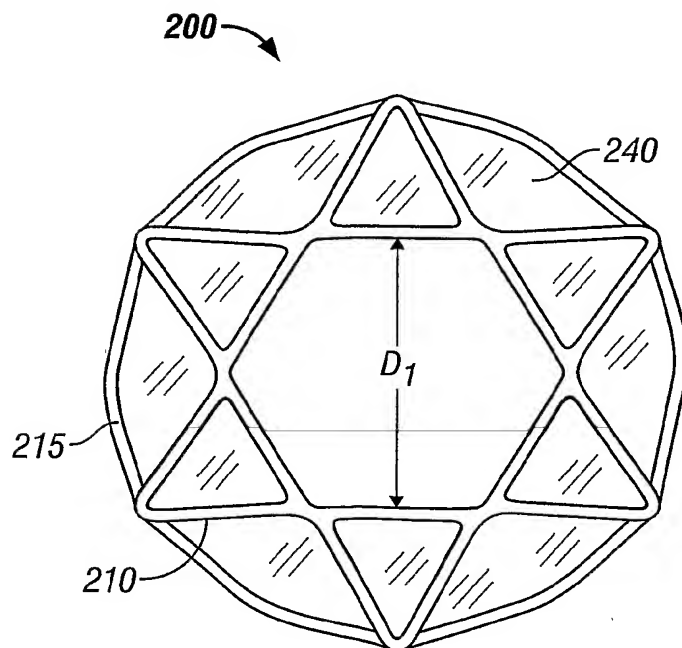
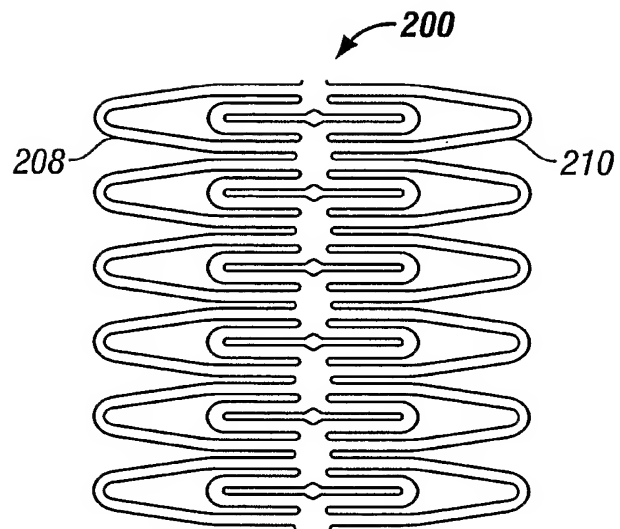
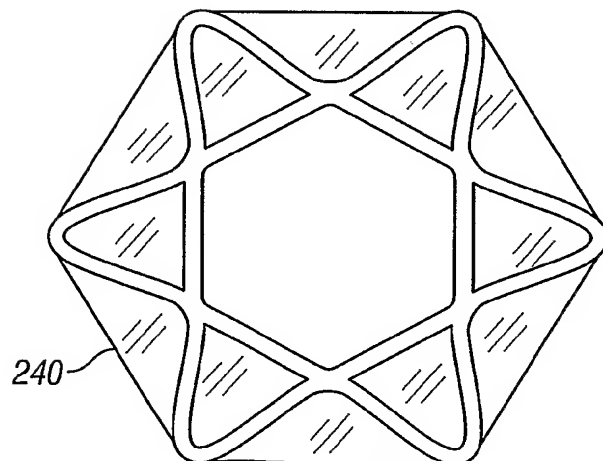


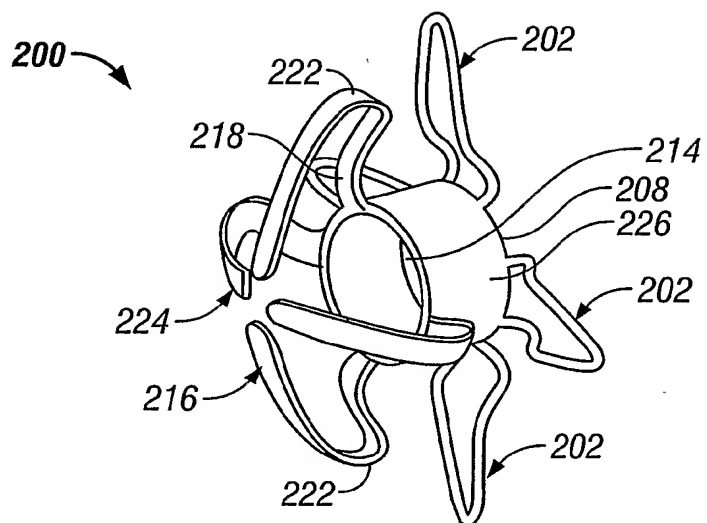
FIG. 14E

**FIG. 14F****FIG. 14G**

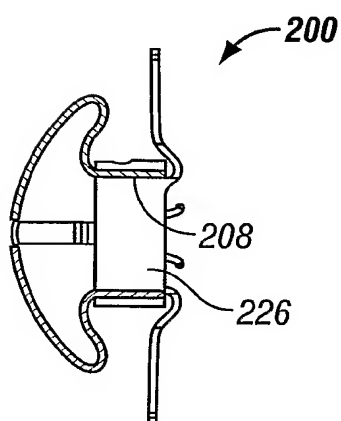
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**FIG. 14H****FIG. 14I**

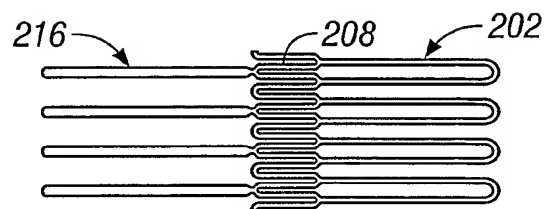
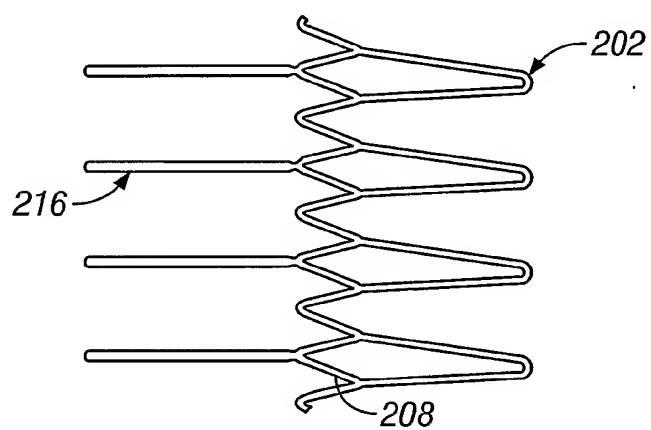
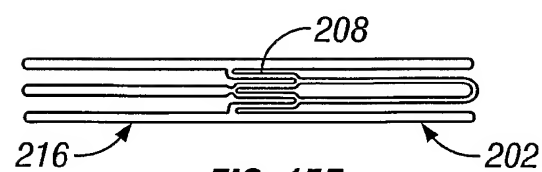
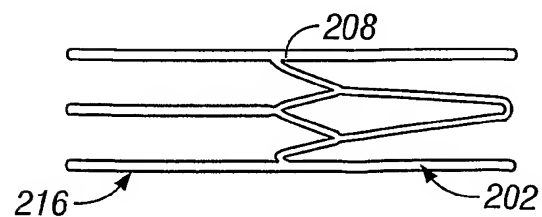
**FIG. 14J****FIG. 14K**



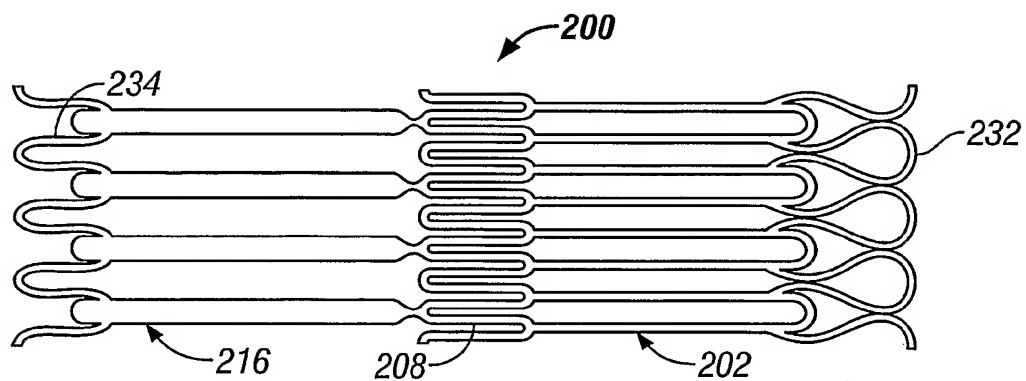
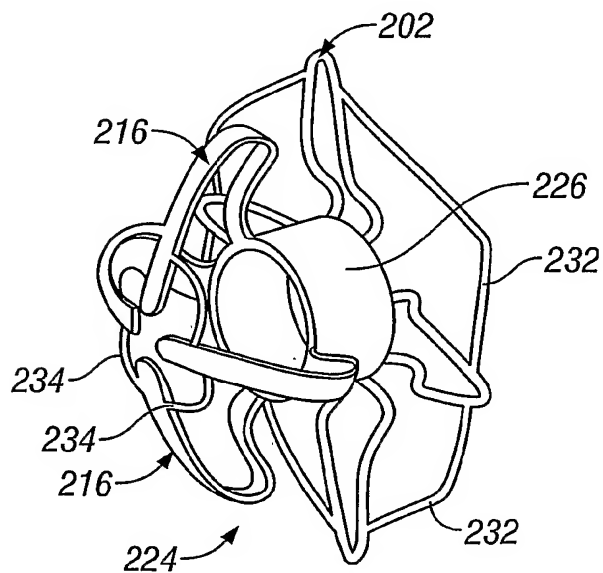
**FIG. 15A**

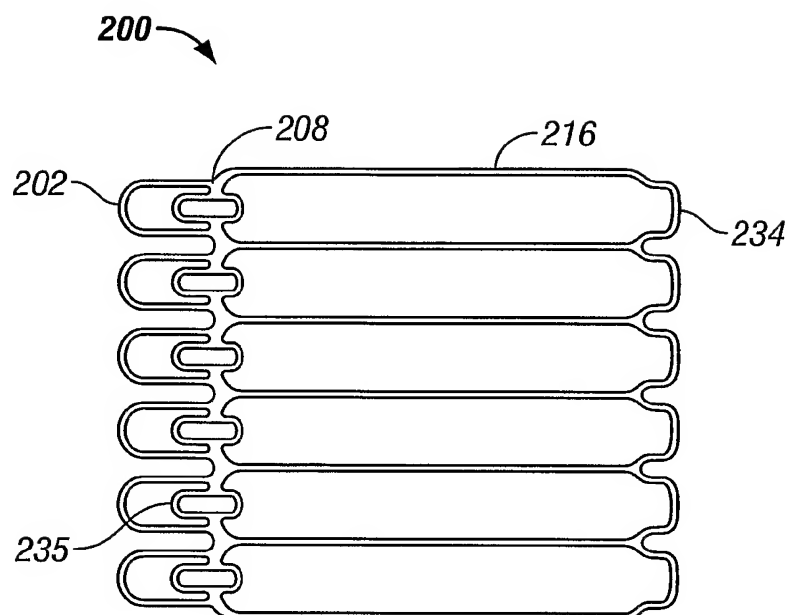
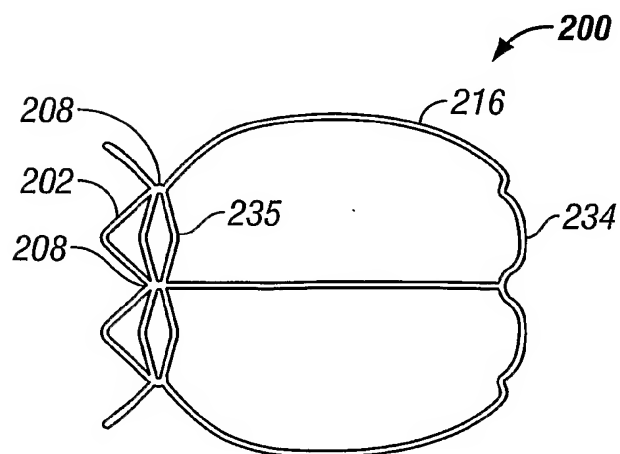


**FIG. 15B**

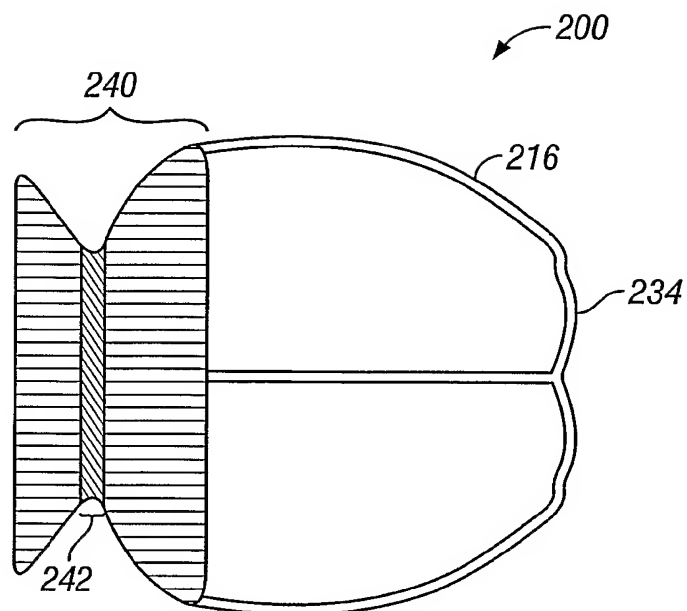
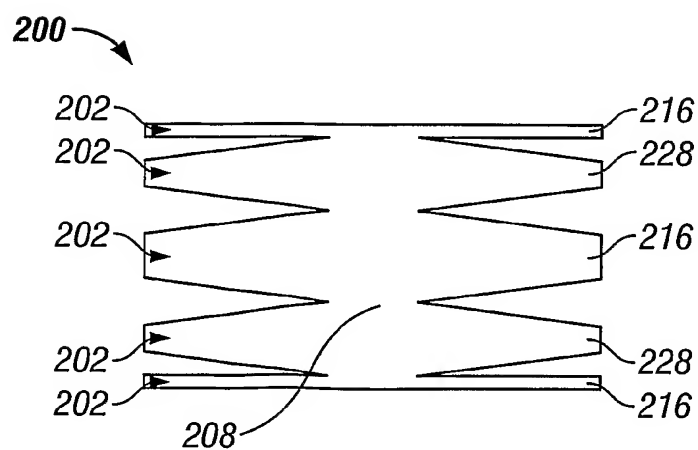
**FIG. 15C****FIG. 15D****FIG. 15E****FIG. 15F**

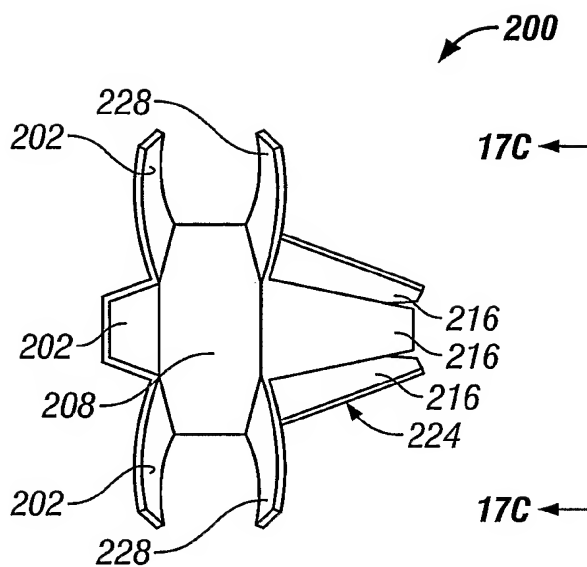
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**FIG. 16A****FIG. 16B**

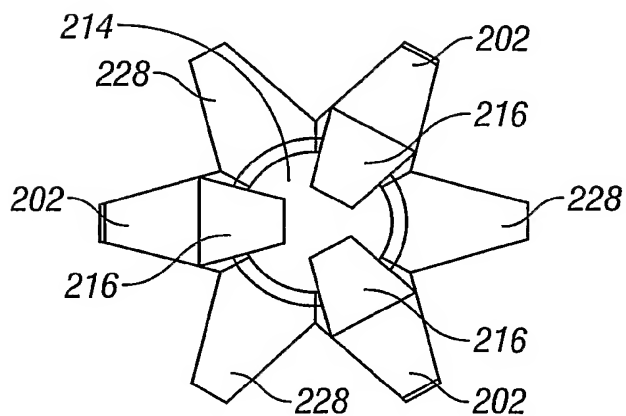
**FIG. 16C****FIG. 16D**



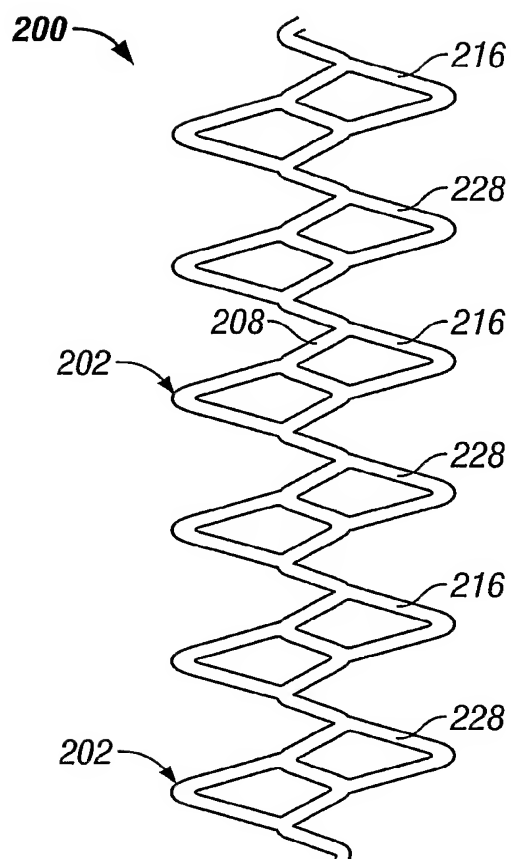
**FIG. 16E****FIG. 17A**



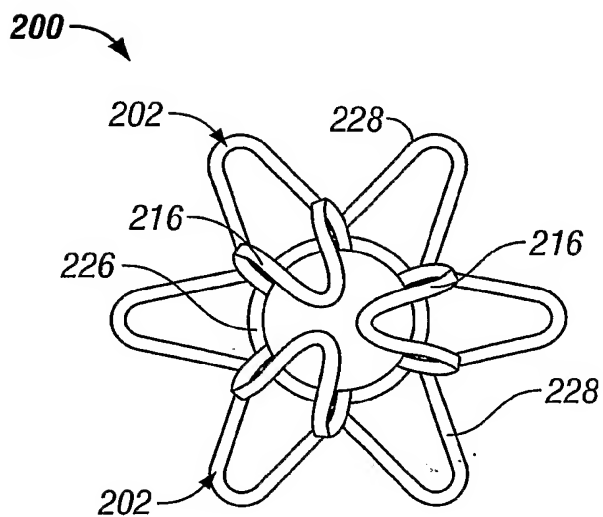
**FIG. 17B**



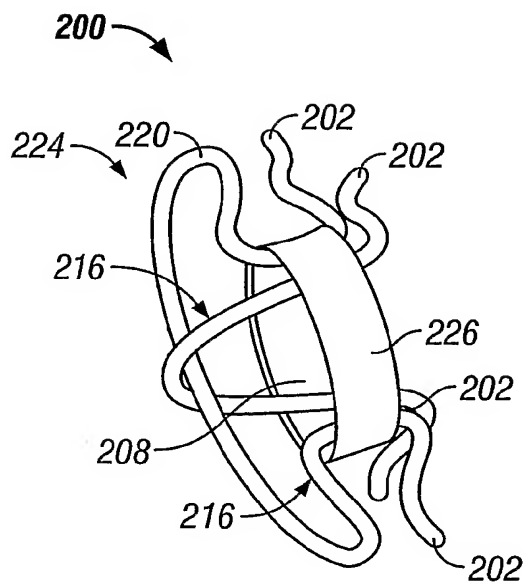
**FIG. 17C**



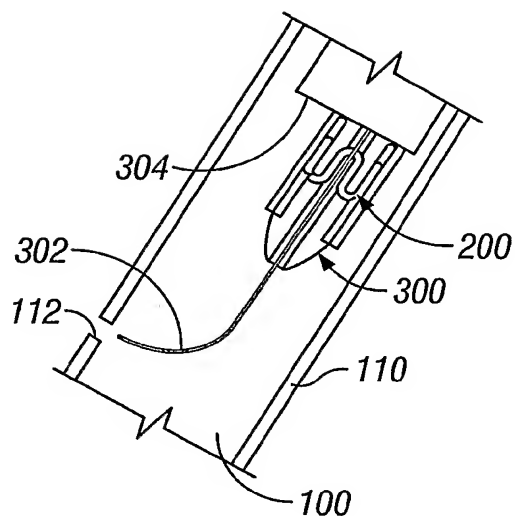
**FIG. 17D**



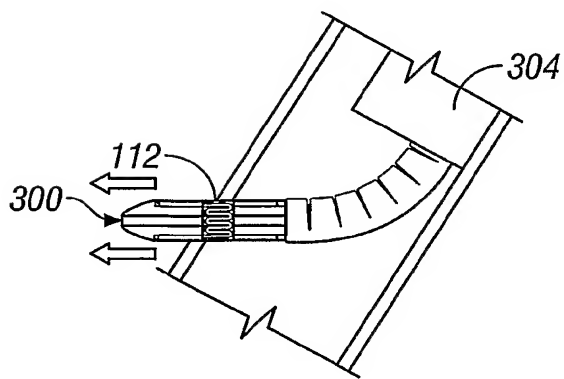
**FIG. 17E**



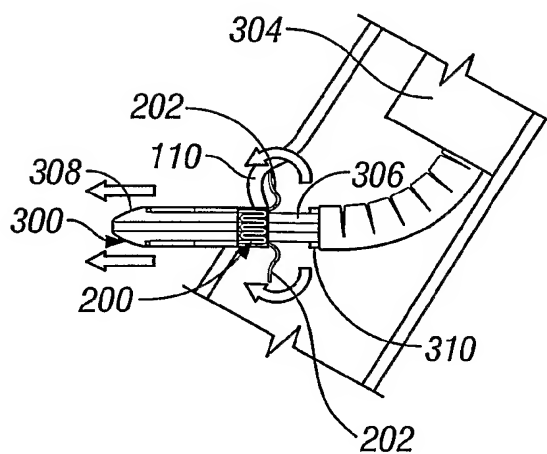
**FIG. 17F**



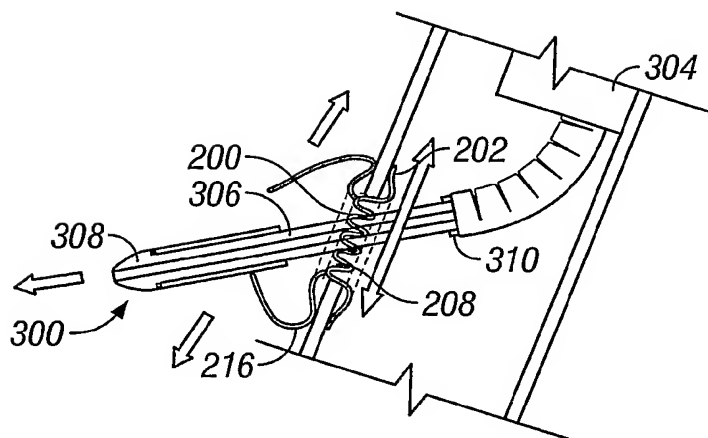
**FIG. 18A**



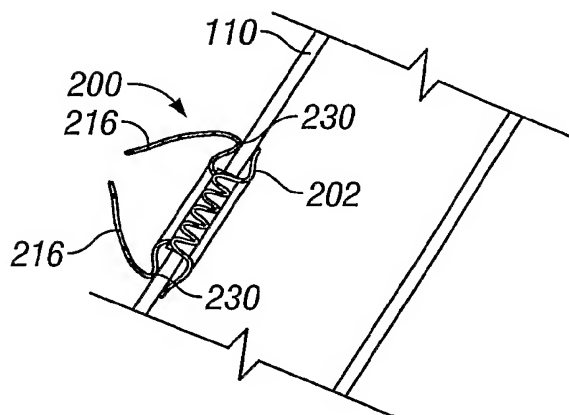
**FIG. 18B**



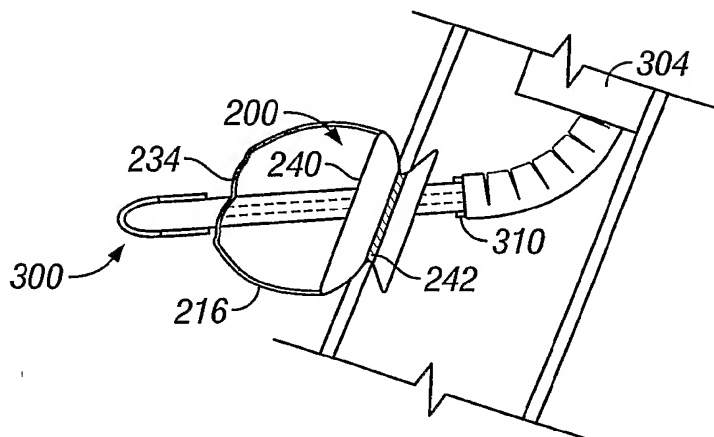
**FIG. 18C**



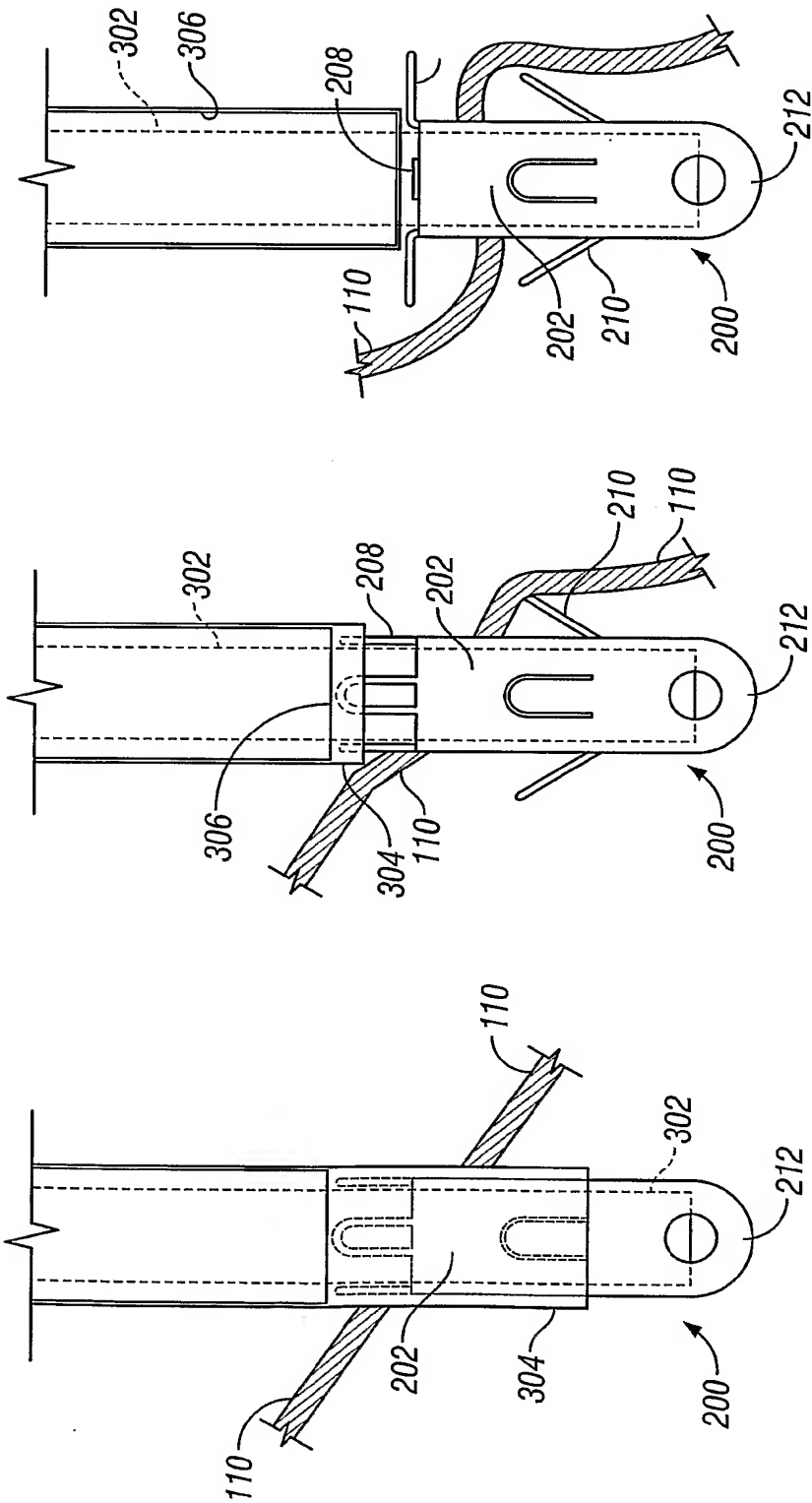
**FIG. 18D**



**FIG. 18E**



**FIG. 18F**



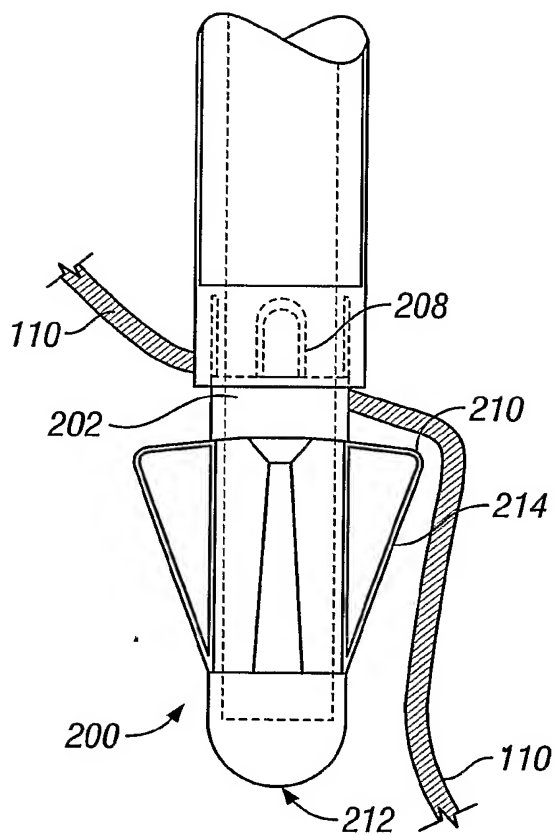


FIG. 20A

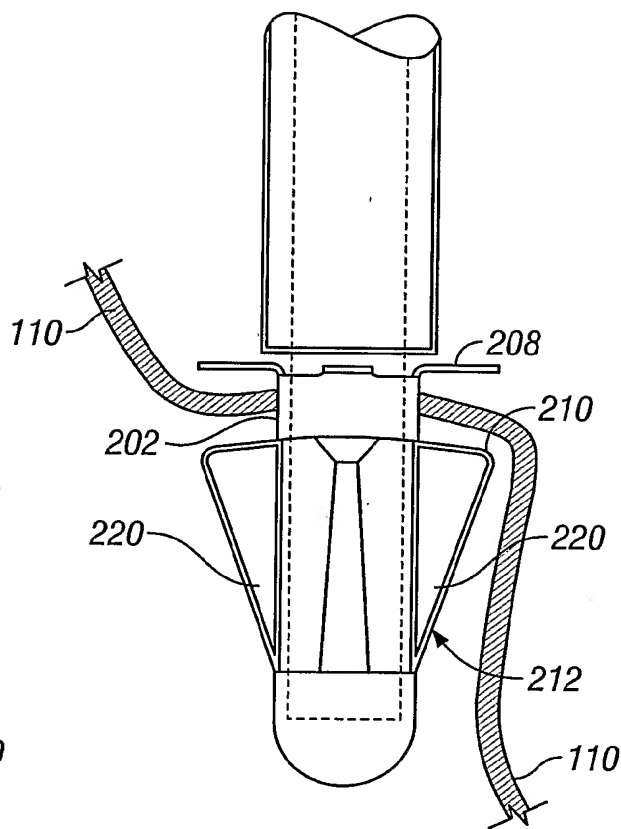


FIG. 20B

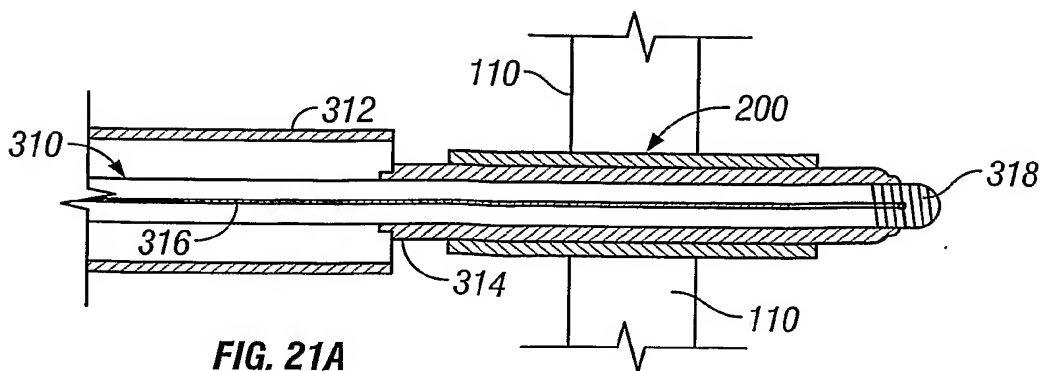
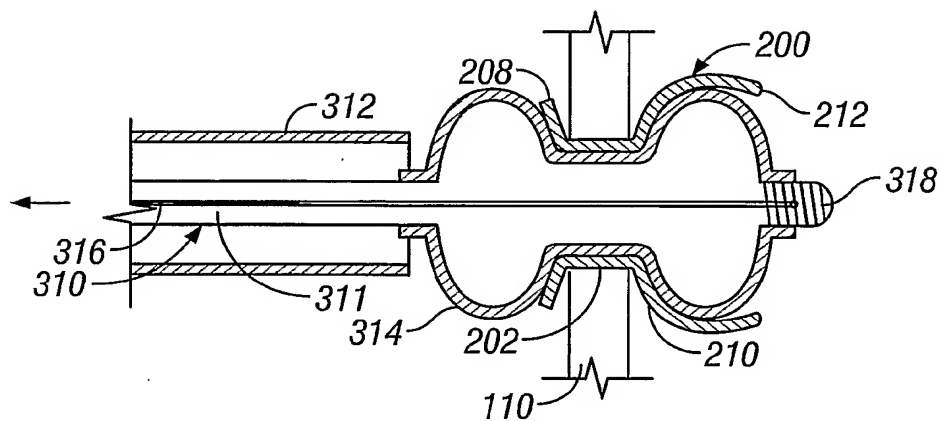
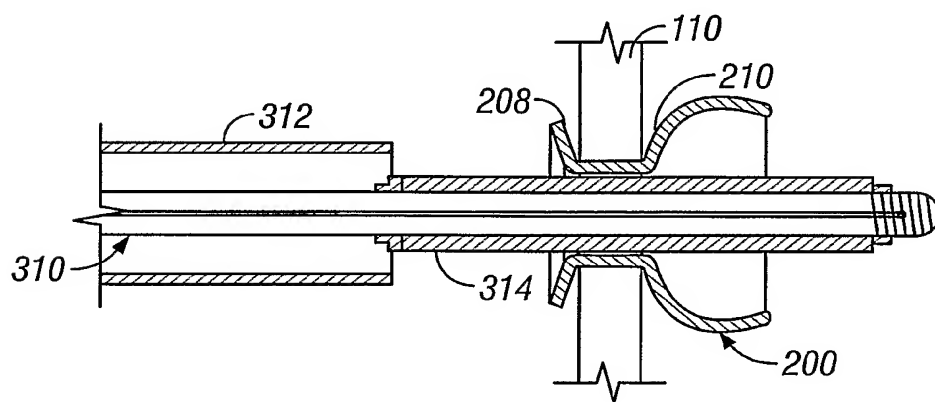


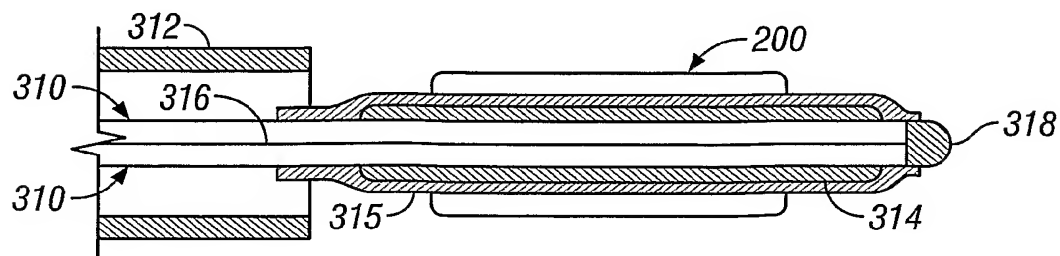
FIG. 21A



**FIG. 21B**

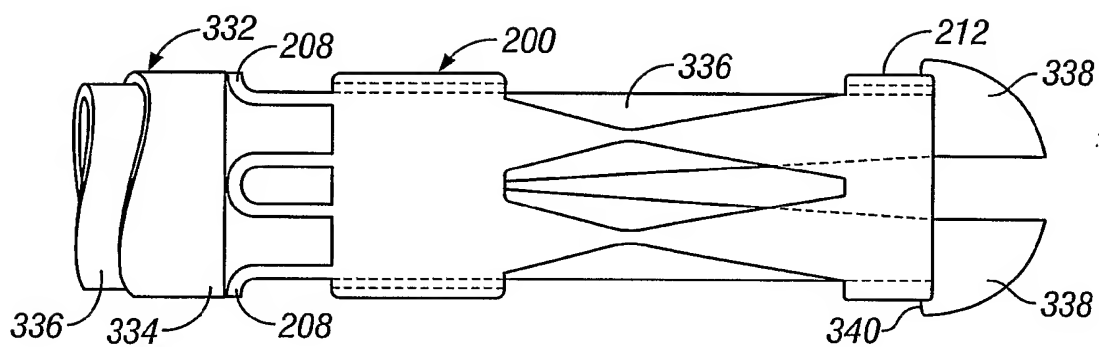


**FIG. 21C**

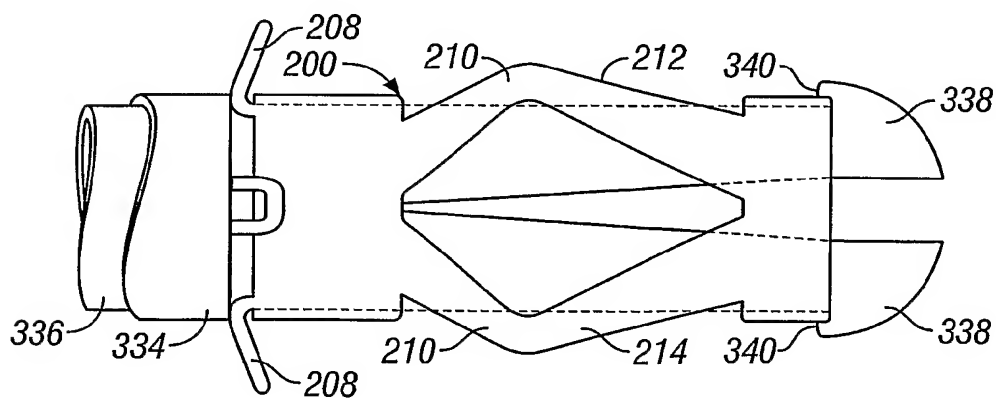


**FIG. 21D**

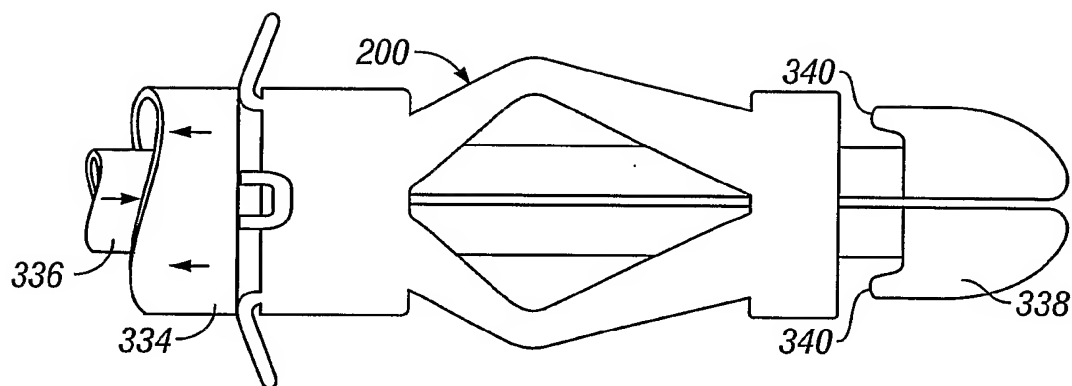




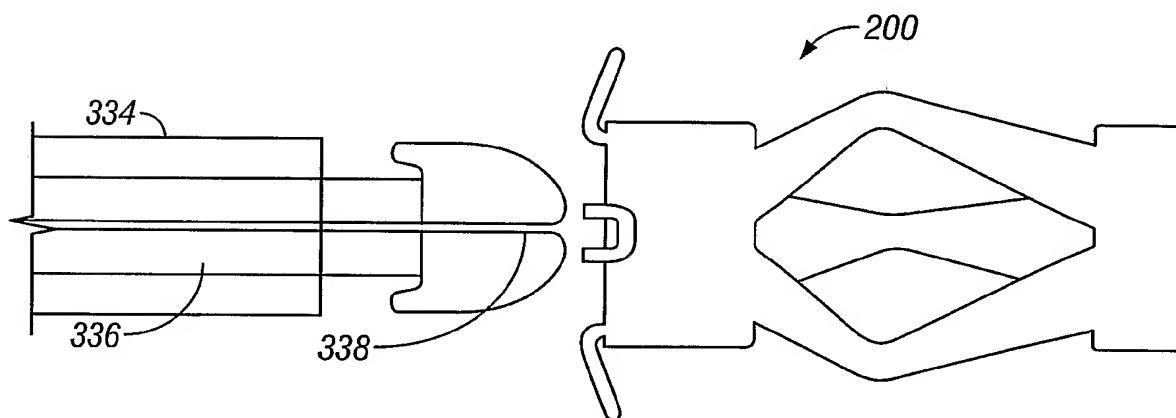
**FIG. 22A**



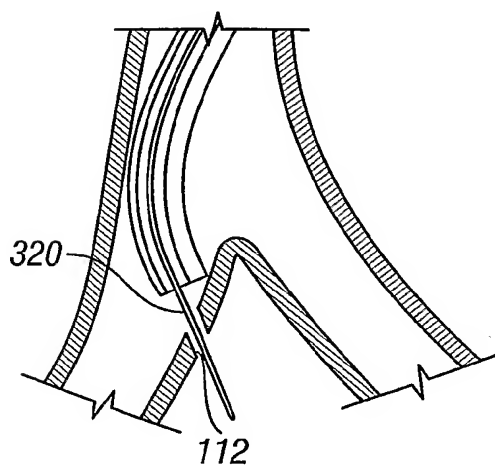
**FIG. 22B**



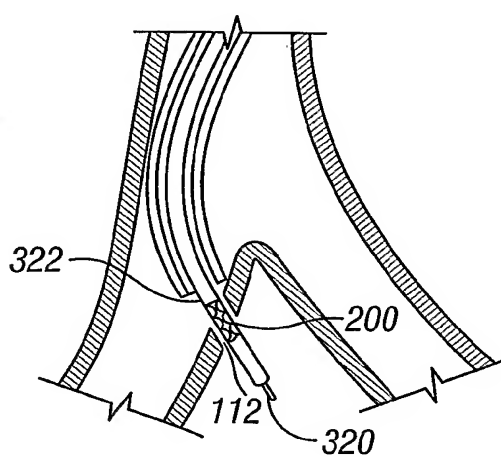
**FIG. 22C**



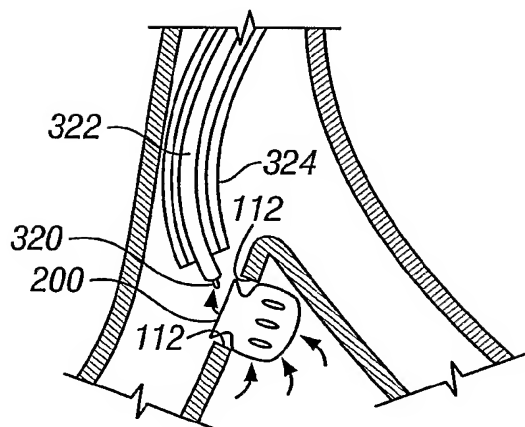
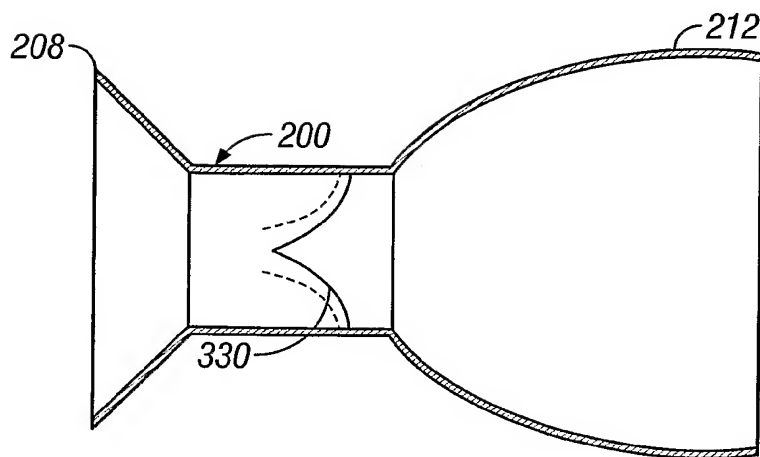
**FIG. 22D**

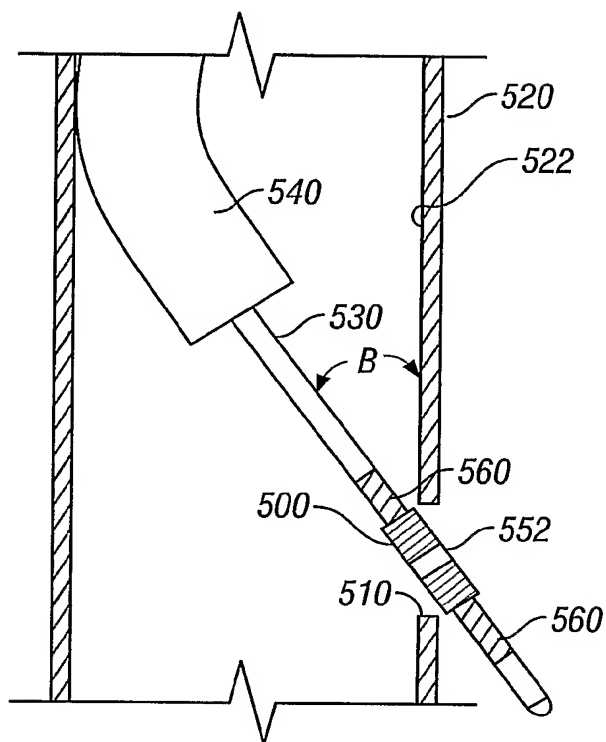


**FIG. 23A**

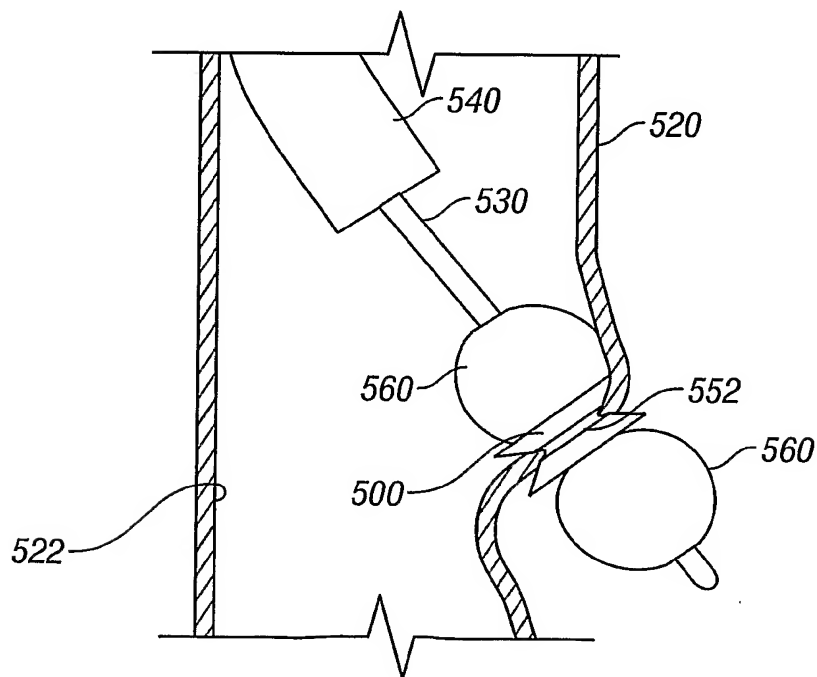


**FIG. 23B**

**FIG. 23C****FIG. 24**



**FIG. 25A**



**FIG. 25B**

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/28237

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 18/18

US CL : 606/41

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/41; 604/165.01, 167.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,645,559 A (HACHTMAN et al) 08 July 1997, see entire document.	1-70
A	US 5,674,277 A (FREITAG) 07 October 1997, see entire document.	1-70
A	US 5,693,085 A (BUIRGE et al) 02 December 1997, see entire document.	1-70

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

08 November 2002 (08.11.2002)

Date of mailing of the international search report

15 APR 2003

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

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Authorized Officer

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Telephone No. (703) 308-1148

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/28237

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.